journal of wound care JWC
VOLUME 30. NUMBER 7 JULY 2021

# Cost-effectiveness of using intermittent pneumatic compression to manage hard-to-heal venous leg ulcers in the UK

**Julian F Guest,**[1] PhD, Health Economist*; **Karen Staines,**[2] RGN, BSc, Director of Education and Research and Clinical Lead for Wound Care; **Nina Murphy,**[3] RGN, BSc, Clinical Lead for Tissue Viability
***Corresponding author email:** julian.guest@catalyst-health.com

**1** Catalyst Consultants, Poole, UK. **2** Accelerate CIC, St Joseph's Hospice, London, UK.
**3** NELFT Community Services, NELFT NHS Foundation Trust, London, UK.

# Cost-effectiveness of using intermittent pneumatic compression to manage hard-to-heal venous leg ulcers in the UK

**Objective:** To estimate whether thigh-administered intermittent pneumatic compression (IPC) could potentially afford the UK's National Health Service (NHS) a cost-effective intervention for the management of hard-to-heal venous leg ulcers (VLUs).
**Method:** A Markov model was constructed depicting the management of hard-to-heal VLUs with IPC plus standard care or standard care alone over a period of 24 weeks. The model estimated the cost-effectiveness of the two interventions in terms of the incremental cost per quality-adjusted life year (QALY) gained at 2019/20 prices.
**Results:** Treatment of hard-to-heal VLUs with IPC plus standard care instead of standard care alone is expected to increase the probability of healing by 58% (from 0.24 to 0.38) at 24 weeks and increase health-related quality of life over 24 weeks from 0.32 to 0.34 QALYs per patient. Additionally, the cost of treating with IPC plus standard care (£3,020 per patient) instead of standard care alone (£3,037 per patient) has the potential to be cost-neutral if use of this device is stopped after 6 weeks in non-improving wounds. Sensitivity analysis showed that the relative cost-effectiveness of IPC plus standard care remains <£20,000 per QALY with plausible variations in costs and effectiveness.
**Conclusion:** Within the limitations of this study, the addition of IPC to standard care potentially affords a cost-effective treatment to the NHS for managing hard-to-heal VLUs. However, a controlled study is required to validate the outcomes of this analysis.
**Declaration of interest:** This study was commissioned and funded by Huntleigh Healthcare Ltd, Cardiff, UK. The study's sponsors had no involvement in the study design, analysis and interpretation of the data, and the writing of this manuscript. The views expressed in this article are those of the authors and not necessarily those of the sponsors. The authors have no other conflicts of interest to declare.

**compression • cost-effectiveness • health economics • infection • intermittent pneumatic compression (IPC) • UK • ulcer • venous • venous leg ulcer • wound**

Venous leg ulcers (VLUs) are a major cause of morbidity and decreased health-related quality of life (HRQoL).[1] The prevalence of VLUs in adults over 18 years of age in the UK was estimated to be 0.6 per 100 individuals in 2012/13,[2,3] rising to 1 per 100 individuals in 2017/18,[4] with some patients experiencing a repeated cycle of ulceration, healing and recurrence. VLUs arise from chronic venous insufficiency in the lower limbs, for which the main risk factors include family history, deep venous thrombosis, age and obesity.[5]

The mainstay of treatment for established venous insufficiency includes the use of compression to apply mechanically controlled pressure to the surface of the lower limbs, with the aim of improving venous function.[6,7] The time to VLU healing can range from several weeks to months;[8] however, some ulcers become hard-to-heal since they fail to heal in an orderly and timely manner.[9] These wounds may benefit from the use of appropriate advanced therapies that have the potential to facilitate wound healing and improve outcomes.[10]

One such advanced therapy is intermittent pneumatic compression (IPC). This technology uses an electronically-controlled pump to apply controlled mechanical cyclical pressure to the limbs by means of compressed air through specialised encircling garments. Pressure, inflation, deflation and hold times all vary depending on the device's manufacturer and clinical indication. The encircling garment can be single-chambered or multi-chambered, providing uniform or sequential pressure, respectively, in a distal to proximal direction.[11,12] IPC can potentially facilitate venous return by simulating a calf muscle pump in those with venous insufficiency.

One such IPC device, WoundExpress (Huntleigh Healthcare Ltd., UK), has been designed to be applied in the thigh region of the affected limb in patients with lower limb ulceration of both venous and mixed aetiologies. The WoundExpress compression system consists of a circumferential three-chamber thigh garment and an electronic pneumatic compression pump operating over a repeated 4-minute cycle. This device has been investigated in two prospective observational studies in patients with a hard-to-heal venous or mixed leg ulcer in England and Wales, defined as 'wounds failing to progress over the preceding 8-week period'.[13,14] Those recruited into the study were treated

**Julian F Guest**,[1] PhD, Health Economist*; **Karen Staines**,[2] RGN, BSc, Director of Education and Research and Clinical Lead for Wound Care; **Nina Murphy**,[3] RGN, BSc, Clinical Lead for Tissue Viability
***Corresponding author email:** julian.guest@catalyst-health.com
**1** Catalyst Consultants, Poole, UK. **2** Accelerate CIC, St Joseph's Hospice, London, UK. **3** NELFT Community Services, NELFT NHS Foundation Trust, London, UK.

with standard care (i.e., the combination of dressings, compression therapy and other bandages that patients would receive in clinical practice[8]) in addition to IPC, which was applied for 2 hours per day for a total of 8 or 16 weeks. Patients were advised to elevate their limb while using the IPC. These patients had a mean age of 71.9 years, 71% were male and their wound duration was a mean of 52.5 months per ulcer. The healing rate in the cohort of patients at the Welsh centres (n=21) was reported to be 10% at 8 weeks and a further 85% were progressing towards healing.[13] The healing rate in the cohort of patients at the English centres (n=16) was reported to be 41% at 16 weeks and 51% were progressing towards healing.[14]

Thigh-administered IPC has been investigated in a total of 45 patients with a hard-to-heal VLU in England and Wales. The aim of this health economic study was to use the findings from this observational study to assess whether using thigh-administered IPC affords the NHS a cost-effective technology with which to treat hard-to-heal VLUs.

**Fig 1.** Markov model
IPC—intermittent pneumatic compresssion; VLU—venous leg ulcer

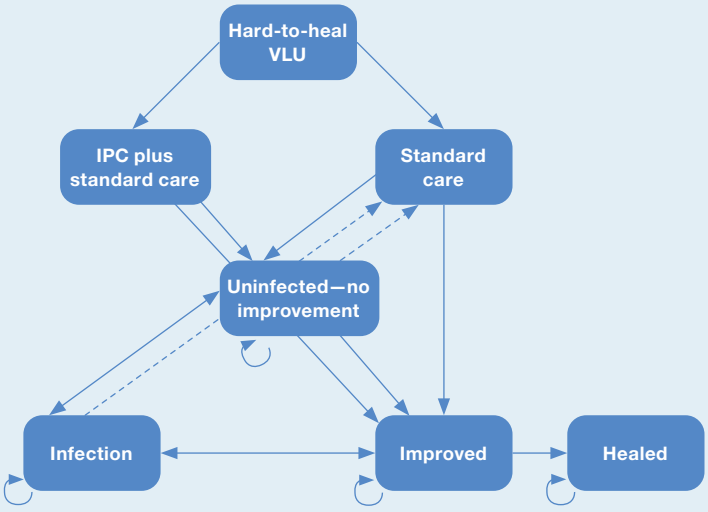
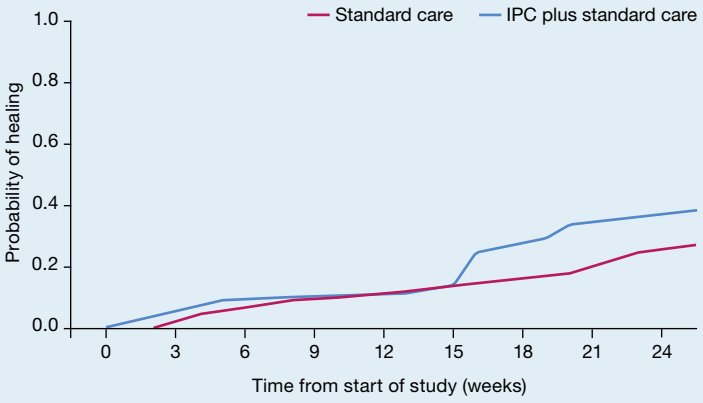



**Fig 2.** Kaplan–Meier time-to-healing projection
IPC—intermittent pneumatic compresssion




## Method

### Study design

This was a modelling study based on a retrospective cohort analysis of patients with a hard-to-heal VLU.

### Economic modelling

A Markov model was constructed in Excel depicting the management of hard-to-heal VLUs with thigh-administered IPC in addition to standard care or standard care alone over a period of 24 weeks (Fig 1). The model comprised the following four health states: uninfected ulcer, infected ulcer, improved ulcer and healed ulcer. Patients enter the model with a hard-to-heal uninfected ulcer. Patients either remain in this health state or move to one of the other health states and transition weekly for a total of 24 weeks. The model was populated with a combination of transition probabilities, clinical outcomes, resource utilisation estimates and published utilities for VLUs as described below.

### Study population

The observational study had no comparator group. Therefore, the study population comprised the cohort of patients with a hard-to-heal VLU who participated in the observational study of thigh-administered IPC and a matched sample of patients, obtained from the real-world evidence Health Improvement Network (THIN) database, who were managed with standard care in clinical practice. (THIN is a registered trademark of Cegedim SA in the UK and other countries. Reference made to the THIN database is intended to be descriptive of the data asset licensed by IQVIA.)

### Ethical approval

The observational studies were conducted under the remit of a service evaluation so NHS ethics approval was not required. In addition, individual sites obtained approval from their local R & D departments. Patient consent was not required.

### IPC cohort

Thigh-administered IPC was recently evaluated among a cohort of 45 patients with a hard-to-heal VLU in England and Wales. Patients' age was a mean of 69.0±13.5 years, 67% of the cohort was male and their wound duration before the start of IPC was a mean of 3.6±4.3 years per VLU.

Patients were followed up for 8 or 16 weeks in the observational study. Time-series forecasting was undertaken to interpolate missing wound sizes between baseline and the last date of follow-up of each individual patient and to predict wound sizes up to 24 weeks. Kaplan–Meier analysis was also used to estimate the probability of healing up to 24 weeks from the start of IPC (Fig 2). Over 24 weeks from the start of treatment,

**Table 1a: Weekly transition probabilities in the intermittent pneumatic compression (IPC) plus standard care arm of the Markov model**

| Week | Uninfected wound | Improving wound | Healing | Healed | Infected wound: continue with IPC | Infected wound: stop IPC and remain on standard care | Non-improving wound: stop IPC and remain on standard care |
|---|---|---|---|---|---|---|---|
| 0 | 0.422 | 0.444 | 0.000 | 0.000 | 0.133 | 0.000 | 0.000 |
| 1 | 0.422 | 0.444 | 0.000 | 0.000 | 0.133 | 0.000 | 0.000 |
| 2 | 0.422 | 0.400 | 0.044 | 0.000 | 0.111 | 0.000 | 0.022 |
| 3 | 0.378 | 0.422 | 0.000 | 0.044 | 0.111 | 0.022 | 0.022 |
| 4 | 0.422 | 0.378 | 0.000 | 0.022 | 0.133 | 0.022 | 0.022 |
| 5 | 0.444 | 0.311 | 0.044 | 0.022 | 0.111 | 0.022 | 0.044 |
| 6 | 0.467 | 0.289 | 0.022 | 0.067 | 0.089 | 0.022 | 0.044 |
| 7 | 0.467 | 0.289 | 0.000 | 0.089 | 0.089 | 0.022 | 0.044 |
| 8 | 0.444 | 0.289 | 0.000 | 0.089 | 0.089 | 0.044 | 0.044 |
| 9 | 0.422 | 0.289 | 0.000 | 0.089 | 0.111 | 0.044 | 0.044 |
| 10 | 0.444 | 0.289 | 0.000 | 0.089 | 0.089 | 0.044 | 0.044 |
| 11 | 0.444 | 0.289 | 0.000 | 0.089 | 0.067 | 0.067 | 0.044 |
| 12 | 0.489 | 0.289 | 0.000 | 0.089 | 0.022 | 0.067 | 0.044 |
| 13 | 0.489 | 0.267 | 0.022 | 0.089 | 0.022 | 0.067 | 0.044 |
| 14 | 0.489 | 0.267 | 0.000 | 0.111 | 0.022 | 0.067 | 0.044 |
| 15 | 0.489 | 0.244 | 0.022 | 0.111 | 0.022 | 0.067 | 0.044 |
| 16 | 0.489 | 0.133 | 0.111 | 0.133 | 0.022 | 0.067 | 0.044 |
| 17 | 0.489 | 0.111 | 0.022 | 0.244 | 0.022 | 0.067 | 0.044 |
| 18 | 0.489 | 0.111 | 0.000 | 0.267 | 0.022 | 0.067 | 0.044 |
| 19 | 0.489 | 0.089 | 0.022 | 0.267 | 0.022 | 0.067 | 0.044 |
| 20 | 0.444 | 0.089 | 0.044 | 0.289 | 0.022 | 0.067 | 0.044 |
| 21 | 0.444 | 0.067 | 0.022 | 0.333 | 0.022 | 0.067 | 0.044 |
| 22 | 0.444 | 0.044 | 0.022 | 0.356 | 0.022 | 0.067 | 0.044 |
| 23 | 0.444 | 0.044 | 0.000 | 0.378 | 0.022 | 0.067 | 0.044 |
| 24 | 0.444 | 0.044 | 0.000 | 0.378 | 0.022 | 0.067 | 0.044 |

it was estimated that 38% of all VLUs would heal, 47% of wounds would develop an infection and 11% of patients would discontinue treatment with IPC. The weekly rates of wound healing, improvement and infection among these patients were used to estimate transition probabilities with which the IPC arm of the model was populated (Table 1a).

### Matched cohort from the THIN database

The 45 IPC-treated patients were matched with an equal number of patients from the health economist author's cohort of patients with a VLU managed with standard care alone, obtained from the THIN database.[8] Patients were matched according to their age at the start of treatment, gender and wound duration (Table 2). This was achieved by identifying every patient in our THIN data set who matched these criteria. A representative sample of 45 patients was then generated by random selection of this cohort. No statistically significant differences were found between the IPC and matched THIN cohorts when tested with either a Mann–Whitney U-test or Chi-square test (Table 2).

Standard care in the THIN cohort comprised the combination of dressings, compression therapy and other bandages that the patients with a VLU received in clinical practice,[8] and so reflects real-world care for VLUs. Based on documentation in the electronic records of the patients in the THIN data set, it was estimated that 24% of all VLUs in the standard care arm would heal by 24 weeks and 51% would develop a putative infection. The weekly rates of wound healing, improvement and infection among these patients were used to estimate transition probabilities with which the standard care arm of the model was populated (Table 1b).

### Utilities

Utility scores express patient preferences for specific health states, which can be used to estimate a patient's HRQoL in terms of the number of quality-adjusted life years (QALYs) gained by an intervention or service. HRQoL was not recorded in the IPC observational studies nor in the THIN database. Hence, published utility scores for VLUs (0.64 for an existing or unhealed VLU, 0.73 for an improving VLU and 1.00 for a healed VLU[15]), obtained from the general public across the UK (some of whom had a VLU) using standard gamble

methodology, were assigned to each health state in the model. This enabled patients' expected HRQoL, in terms of the number of QALYs at 24 weeks from the start of treatment, to be estimated.

### Unit costs

NHS costs of VLU management[3,8] were uprated to 2019/20 prices using NHS Improvement's latest assumptions for NHS provider inflation[16] (Table 3). These costs were applied to the health states in the model to estimate the total healthcare cost of managing a VLU with IPC plus standard care or standard care alone over 24 weeks.

### Model outputs

The primary measure of effectiveness was patients' HRQoL in terms of the number of QALYs at 24 weeks from the time patients entered the model. The secondary measure of effectiveness was the probability of healing by 24 weeks from the time patients entered the model.

The expected NHS cost of patient management over 24 weeks from the time patients entered the model was estimated at 2019/20 prices.

### Cost-effectiveness analysis

The potential cost-effectiveness of including thigh-administered IPC into a standard care protocol compared with standard care alone was calculated as '(the difference between the expected costs of the two treatment strategies) ÷ (the difference in the number of QALYs between the two treatment strategies)', and expressed as the incremental cost per QALY gained. If one of the strategies generated more QALYs for less cost, it was considered to be the dominant intervention.

The cost-effectiveness analysis was undertaken for four scenarios: IPC is continued for up to 16 weeks in wounds that are improving or up to healing if that comes sooner and:

- IPC is stopped after 6 weeks in non-improving wounds, or
- IPC is stopped after 8 weeks in non-improving wounds, or
- IPC is stopped after 10 weeks in non-improving wounds, or
- IPC is stopped after 12 weeks in non-improving wounds.

The analysis did not consider that IPC would be continued for 16 weeks in non-improving wounds.

### Sensitivity analysis

Probabilistic sensitivity analysis was undertaken to evaluate uncertainty within the model. This involved 10,000 iterations of the model by simultaneously varying the different inputs. To estimate the random values of the inputs, the standard error was assumed to be 10% around the mean values, and relevant distributions were assigned to the deterministic values (beta distributions for probabilities and utilities, and

**Table 1b: Weekly transition probabilities in the standard care arm of the Markov model**

| Week | Uninfected wound | Improving wound | Healing | Healed | Infected wound |
|---|---|---|---|---|---|
| 0 | 0.556 | 0.244 | 0.000 | 0.000 | 0.200 |
| 1 | 0.356 | 0.244 | 0.000 | 0.000 | 0.400 |
| 2 | 0.356 | 0.244 | 0.000 | 0.000 | 0.400 |
| 3 | 0.556 | 0.244 | 0.000 | 0.000 | 0.200 |
| 4 | 0.556 | 0.200 | 0.044 | 0.000 | 0.200 |
| 5 | 0.511 | 0.200 | 0.000 | 0.044 | 0.244 |
| 6 | 0.511 | 0.200 | 0.000 | 0.044 | 0.244 |
| 7 | 0.511 | 0.200 | 0.000 | 0.044 | 0.244 |
| 8 | 0.511 | 0.156 | 0.044 | 0.044 | 0.244 |
| 9 | 0.578 | 0.156 | 0.000 | 0.089 | 0.178 |
| 10 | 0.578 | 0.156 | 0.000 | 0.089 | 0.178 |
| 11 | 0.578 | 0.156 | 0.000 | 0.089 | 0.178 |
| 12 | 0.578 | 0.133 | 0.022 | 0.089 | 0.178 |
| 13 | 0.622 | 0.133 | 0.000 | 0.111 | 0.133 |
| 14 | 0.622 | 0.133 | 0.000 | 0.111 | 0.133 |
| 15 | 0.622 | 0.133 | 0.000 | 0.111 | 0.133 |
| 16 | 0.622 | 0.133 | 0.000 | 0.111 | 0.133 |
| 17 | 0.667 | 0.133 | 0.000 | 0.111 | 0.089 |
| 18 | 0.667 | 0.133 | 0.000 | 0.111 | 0.089 |
| 19 | 0.667 | 0.133 | 0.000 | 0.111 | 0.089 |
| 20 | 0.667 | 0.067 | 0.067 | 0.111 | 0.089 |
| 21 | 0.667 | 0.067 | 0.000 | 0.178 | 0.089 |
| 22 | 0.667 | 0.067 | 0.000 | 0.178 | 0.089 |
| 23 | 0.667 | 0.067 | 0.000 | 0.178 | 0.089 |
| 24 | 0.689 | 0.000 | 0.067 | 0.178 | 0.067 |

**Table 2: Study population characteristics**

| | IPC plus standard care | Standard care | p value |
|---|---|---|---|
| Number of patients | 45 | 45 | |
| Number of wounds | 45 | 45 | |
| Mean age per patient (years) | 69.0±13.5 | 68.7±12.9 | ns |
| Median age (years) | 72.0 | 71.0 | |
| Percentage female | 33% | 38% | ns |
| Mean wound duration per VLU (years) | 3.6±4.3 | 2.5±1.9 | ns |
| Median wound duration (years) | 2.0 | 2.0 | |

IPC—intermittent pneumatic compression; ns—not significant

**Table 3: NHS costs of managing venous leg ulcers (VLUs) at 2019/20 prices**

| Resource | NHS Cost |
|---|---|
| Weekly cost of managing an improving wound that goes on to heal | £40.76 |
| Weekly cost of managing a non-healing wound | £131.61 |
| Weekly cost of managing an infected wound | £224.04 |
| IPC garment cost per patient | £136.50 |
| Weekly rental cost of IPC per patient | £56.00 |

IPC—intermittent pneumatic compression

**Table 4: Health outcomes and costs**

| | IPC plus standard care | Standard care |
|---|---|---|
| Probability of the wound being healed by 24 weeks | 0.38 | 0.24 |
| Probability of the wound having improved but not healed at 24 weeks | 0.04 | 0.00 |
| Probability of the wound remaining unchanged at 24 weeks (i.e. not healed or improved) | 0.58 | 0.76 |
| Probability of the wound being infected at 24 weeks | 0.09 | 0.07 |
| Probability of wound infection over 24 weeks | 0.47 | 0.51 |
| Probability of having stopped IPC but continued with standard care | 0.11 | N/A |
| Mean number of QALYs per patient at 24 weeks | 0.34 | 0.32 |
| Mean cost per patient at 24 weeks, if IPC is stopped after 6 weeks in non-improving wounds | £3020 | £3037 |
| Mean cost per patient at 24 weeks, if IPC is stopped after 8 weeks in non-improving wounds | £3082 | £3037 |
| Mean cost per patient at 24 weeks, if IPC is stopped after 10 weeks in non-improving wounds | £3142 | £3037 |
| Mean cost per patient at 24 weeks, if IPC is stopped after 12 weeks in non-improving wounds | £3201 | £3037 |

IPC—intermittent pneumatic compression; QALY—quality-adjusted life year

gamma distributions for resource use and costs), enabling the distribution of costs and QALYs to be estimated. Outputs from this analysis enabled the construction of a cost-effectiveness acceptability curve showing the probability of using IPC in VLU management being cost-effective at different cost per QALY thresholds.

Deterministic sensitivity analyses were performed to assess the effect of independently varying the values of individual parameters within the model over plausible ranges.

### Budget impact analysis

The number of people ≥18 years of age across all English Clinical Commissioning Groups (CCGs) and Scottish and Welsh Health Boards was a mean of 238,000 individuals in 2019.[17–19] Additionally, the prevalence of VLUs among adults aged ≥18 years has been estimated to be 0.6 per 100 individuals per annum, suggesting that an average CCG/Health Board has 1400 VLUs per annum in their catchment population.[2,3] By assuming that 40% of these VLUs are hard-to-heal ulcers,[8] it would suggest that there are 560 hard-to-heal VLUs in the catchment population of an average CCG/Health Board annually.

The budget impact analysis assumed that these 560 hard-to-heal VLUs would be eligible to be managed with IPC plus standard care. Hence, the annual budget impact to an average CCG/Health Board was estimated by treating varying percentages of 560 VLUs with IPC plus standard care and standard care alone.

## Results

### Clinical outcomes and healthcare costs

The probability of healing by 24 weeks among the IPC-treated patients was 0.38 compared with 0.24 among the standard care-treated patients (Table 4). Hence, treatment of hard-to-heal VLUs with IPC plus standard care instead of standard care alone is expected to increase the probability of healing by 58% by 24 weeks. Consequently, patients treated with IPC experienced a correspondingly better HRQoL (Table 4).

The expected cost of managing a VLU with IPC in addition to standard care, if IPC is stopped after 6 weeks in the non-improving wounds, was £3020 per patient compared with £3037 per patient managed with standard care alone (Table 4). The device accounted for 18% (£548) of the cost of managing the patients treated with IPC. The cost per patient treated with IPC plus standard care increased in accordance with increasing length of time the device was used to treat the non-improving wounds (Table 4).

### Cost-effectiveness analysis

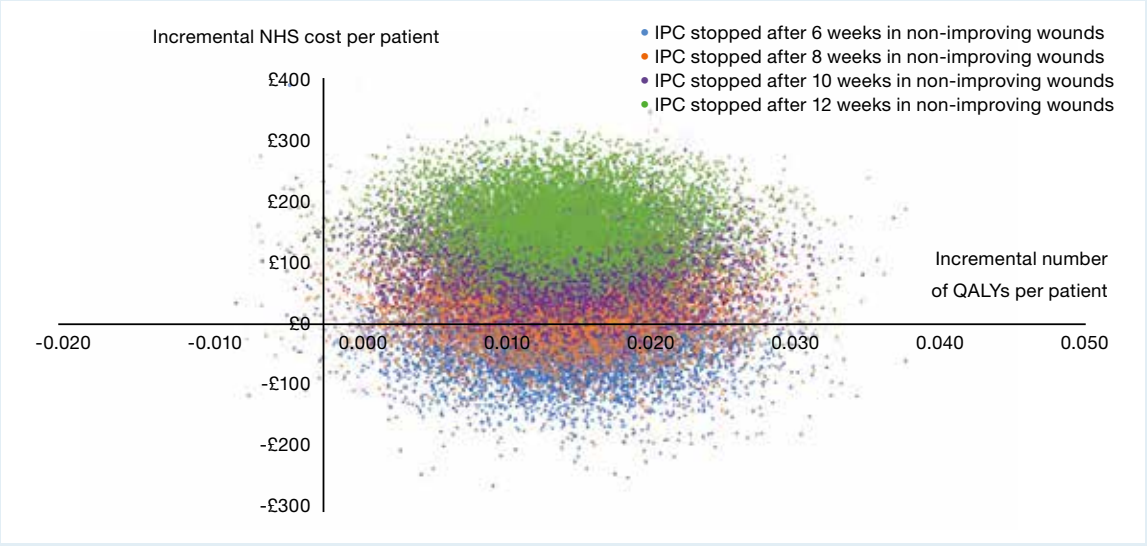
Outputs from the model showed that use of IPC plus standard care, instead of standard care alone, is expected to lead to a cost decrease of £17 over 24 weeks if IPC is stopped after 6 weeks in non-improving wounds, and a corresponding increase of 0.02 QALYs (Table 5). Hence, including IPC into a standard care protocol could potentially afford the NHS a dominant treatment, since

**Table 5: Cost-effectiveness analysis**

| Intervention | Expected NHS cost per patient over 24 weeks | Expected number of QALYs per patient at 24 weeks | NHS cost-difference | QALY difference | Incremental cost per QALY gained |
|---|---|---|---|---|---|
| Standard care | £3037 | 0.32 | | | |
| IPC plus standard care with IPC being stopped after 6 weeks in non-improving wounds | £3020 | 0.34 | -£17 | 0.02 | -£850 |
| IPC plus standard care with IPC being stopped after 8 weeks in non-improving wounds | £3082 | 0.34 | £45 | 0.02 | £2250 |
| IPC plus standard care with IPC being stopped after 10 weeks in non-improving wounds | £3142 | 0.34 | £105 | 0.02 | £5250 |
| IPC plus standard care with IPC being stopped after 12 weeks in non-improving wounds | £3201 | 0.34 | £164 | 0.02 | £8200 |

IPC—intermittent pneumatic compression; QALY—quality-adjusted life year

**Fig 3.** Scatterplot of the incremental cost-effectiveness of intermitteent pneumatic compresssion (IPC) plus standard care compared with standard care alone following 10,000 iterations of the model
QALY—quality-adjusted life year




it improves outcomes for less cost. Table 5 also shows how the incremental cost per QALY gained with use of IPC increases in parallel with increasing use of the device in non-improving wounds.

### Sensitivity analyses

Probabilistic sensitivity analyses highlighted the distribution in the incremental costs and QALYs at 24 weeks between each treatment strategy (Fig 3). The graphs indicate that a greater proportion of samples are located in the bottom right-hand (dominant) quadrant in parallel with decreasing use of the device in non-improving wounds. Outputs from the analysis showed that at a cost-effectiveness threshold of £20,000 per QALY, up to 99%, 98%, 94% and 88% of a cohort is expected to be treated cost-effectively with IPC plus standard care, compared with standard care alone, if treatment with the device stops after 6, 8, 10 and 12 weeks in non-improving wounds, respectively (Fig 4).

Deterministic sensitivity analyses (Table 6) showed that IPC's cost-effectiveness is potentially sensitive to changes in:

- Length of time non-improving VLUs are treated with the technology

**Fig 4.** Probability of intermittemt pneumatic compression (IPC) plus standard care being cost-effective compared with standard care alone. QALY—quality-adjusted life year

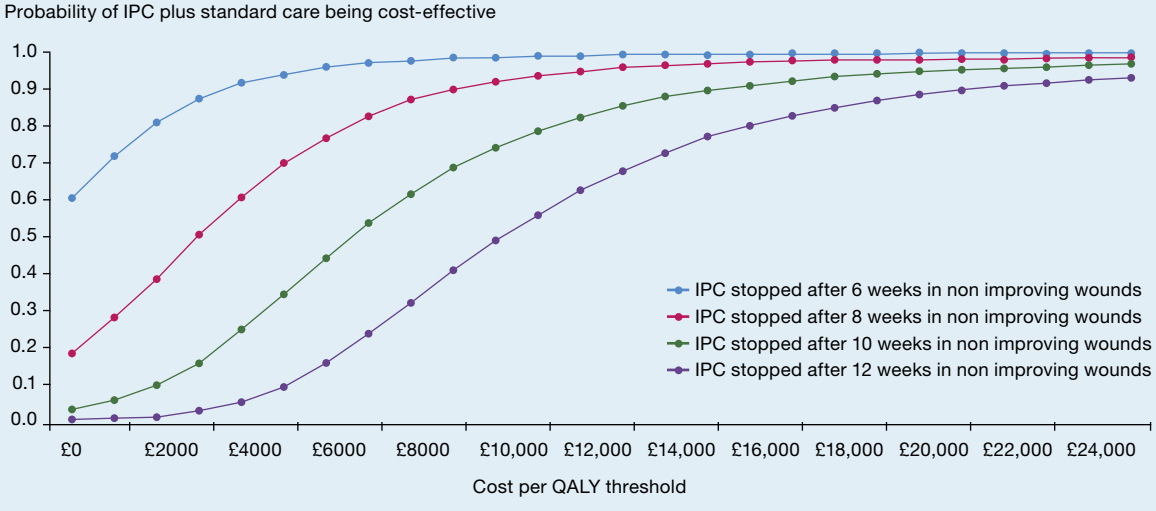


**Table 6: One-way sensitivity analysis**

| | | Range in the incremental cost per QALY gained of using IPC plus standard care compared with standard care alone | | | |
|---|---|---|---|---|---|
| **Scenario** | **Base case** | **If IPC is stopped after 6 weeks in non-improving wounds** | **If IPC is stopped after 8 weeks in non-improving wounds** | **If IPC is stopped after 10 weeks in non-improving wounds** | **If IPC is stopped after 12 weeks in non-improving wounds** |
| Probability of being healed in the IPC plus standard care group at 24 weeks ranges from 0.34 to 0.42 | 0.38 | £6950 to -£8650 | £10,250 to -£5750 | £13,450 to -£2950 | £16,800 to -£400 |
| Probability of being healed in the standard care group at 24 weeks ranges from 0.22 to 0.27 | 0.24 | -£6300 to £8500 | -£3200 to £14,700 | -£200 to £20,700 | £2750 to £26,600 |
| Proportional change in the infection rate in the IPC group ranges by ± 5% | 1.0 | -£1450 to -£200 | £1650 to £2900 | £4650 to £5859 | £7600 to £8750 |
| Proportional change in the infection rate in the standard care group ranges by ± 5% | 1.0 | £150 to -£1850 | £3250 to £1250 | £6250 to £4250 | £9200 to £7200 |
| Proportional change in the cost of wound care ranges by ± 20% | 1.0 | £4850 to -£6450 | £7950 to -£3350 | £10,950 to -£350 | £13,850 to £2550 |
| Difference in the number of QALYs between the two groups ranges from 0.01 to 0.03 | 0.02 | -£1700 to £567 | £4500 to £1500 | £10,500 to £3500 | £16,400 to £5467 |
| The rental cost of IPC ranges from £45 to £66 per week | £56 | -£5050 to £3350 | -£2550 to £7050 | -£50 to £10,550 | £2400 to £14,000 |

IPC-intermittent pneumatic compression; QALY-quality-adjusted life year

**Table 7: Two-way sensitivity analysis showing the range in the incremental cost per quality-adjusted life year (QALY) gained of using intermittent pneumatic compression (IPC) plus standard care compared with standard care alone if IPC is stopped after 6 weeks in non-improving wounds, for simultaneous changes in the probability of healing in both groups. Combination of healing rates with unshaded values favour IPC plus standard care at the £20,000 cost per QALY threshold**

| | | **Probability of being healed in the IPC plus standard care group at 24 weeks** | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | 0.33 | 0.34 | 0.35 | 0.36 | 0.37 | 0.38 | 0.39 | 0.40 | 0.41 | 0.42 |
| **Probability of being healed in the standard care group at 24 weeks** | 0.19 | -£5650 | -£7300 | -£9050 | -£10,650 | -£12,300 | -£13,600 | -£15,550 | -£17,100 | -£18,650 | -£20,400 |
| | 0.20 | -£3100 | -£4750 | -£6500 | -£8100 | -£9750 | -£11,050 | -£13,000 | -£14,550 | -£16,100 | -£17,850 |
| | 0.21 | -£700 | -£2350 | -£4100 | -£5700 | -£7350 | -£8650 | -£10,600 | -£12,150 | -£13,700 | -£15,450 |
| | 0.22 | £1650 | £0 | -£1750 | -£3350 | -£5000 | -£6300 | -£8250 | -£9800 | -£11,350 | -£13,100 |
| | 0.23 | £3900 | £2250 | £500 | -£1100 | -£2750 | -£4050 | -£6000 | -£7550 | -£9100 | -£10,850 |
| | 0.24 | £6050 | £4400 | £2650 | £1050 | -£600 | -£1900 | -£3850 | -£5400 | -£6950 | -£8700 |
| | 0.25 | £8150 | £6500 | £4750 | £3150 | £1500 | £200 | -£1750 | -£3300 | -£4850 | -£6600 |
| | 0.26 | £20,400 | £17,100 | £13,600 | £10,400 | £7100 | £4500 | £600 | -£2500 | -£5600 | -£9100 |
| | 0.27 | £24,400 | £21,100 | £17,600 | £14,400 | £11,100 | £8500 | £4600 | £1500 | -£1600 | -£5100 |
| | 0.28 | £28,300 | £25,000 | £21,500 | £18,300 | £15,000 | £12,400 | £8500 | £5400 | £2300 | -£1200 |
| | 0.29 | £32,100 | £28,800 | £25,300 | £22,100 | £18,800 | £16,200 | £12,300 | £9200 | £6100 | £2600 |

- Probability of healing
- Cost of wound management
- HRQoL impact of the technology
- The weekly rental cost of IPC.

However, within plausible ranges of these parameters, the use of IPC plus standard care in the treatment of VLUs remains a cost-effective technology because its relative cost-effectiveness remains <£20,000 per QALY. Furthermore, sensitivity analysis found that as long as the 24 weeks healing rate among patients treated with IPC plus standard care is ≥0.33, and that among standard care-treated patients is <0.26, then the incremental cost per QALY gained with this technology would be <£20,000 per QALY (Table 7).

### Budget impact of IPC

If the whole cohort of 560 hard-to-heal VLUs in an average CCG/Health Board were managed with IPC plus standard care instead of standard care alone, the analysis suggests that the number of healed patients would increase by 59% (Table 8). Furthermore, if the use of IPC stopped after 6 weeks in non-improving wounds, the increased healing rate would be cost-neutral for an average CCG/Health Board (Table 8).

## Discussion

A recent Cochrane review of published evidence concluded that IPC may increase healing of VLUs when compared with no compression.[20] There was also some evidence indicating that IPC may improve healing

**Table 8: Budget impact of treating 560 hard-to-heal venous leg ulcers (VLUs) with intermittent pneumatic compression (IPC) plus standard care and standard care alone**

| | Percentage of patients treated with standard care alone compared with IPC plus standard care | | | | |
|---|---|---|---|---|---|
| | 100% : 0% | 75% : 25% | 50% : 50% | 25% : 75% | 0% : 100% |
| Number of healed patients | 134 | 154 | 174 | 193 | 213 |
| NHS cost of treating 560 patients over 24 weeks if: | | | | | |
| IPC is stopped after 6 weeks in non-improving wounds | £1,700,720 | 1,698,340 | 1,695,960 | 1,693,580 | £1,691,200 |
| IPC is stopped after 8 weeks in non-improving wounds | £1,700,720 | 1,707,020 | 1,713,320 | 1,719,620 | £1,725,920 |
| IPC is stopped after 10 weeks in non-improving wounds | £1,700,720 | 1,715,420 | 1,730,120 | 1,744,820 | £1,759,520 |
| IPC is stopped after 12 weeks in non-improving wounds | £1,700,720 | 1,723,680 | 1,746,640 | 1,769,600 | £1,792,560 |

when added to standard compression.[20] However, the review was based on a number of small-to-medium-sized studies, which were open to bias.[20] The review could find no evidence as to how long IPC should be used, and no evidence to elucidate an optimum IPC regimen.[20] Nevertheless, the review indicated that the healing rate was higher when a 'fast' IPC therapy was used (i.e., IPC inflation and deflation of compression was delivered quicker) than with a 'slow' IPC therapy.[20] There was also some evidence of patients experiencing less pain with IPC compared with compression alone.[20] Other systematic reviews found IPC devices to be beneficial in treating patients with critical limb ischaemia[21] and lymphoedema.[21] The authors of these reviews all commented that further trials are required to determine the reliability of the current evidence and the optimum treatment regimen.

This present analysis adopted a Markov modelling approach because that was considered the most representative way to simulate patients' transition between different infected and non-infected health states. The model's health states were mutually exclusive and so each patient represented in the model could be in only one of these disease states at any given time during the time horizon of the model. The resulting model was based on an indirect comparison of the 45 patients who participated in the IPC observational study,[13,14] with 45 matched patients randomly extracted from our THIN data set of patients with a VLU who were managed in clinical practice in the UK[8] (since there was no comparator group in the observational study), in combination with published utilities derived from individuals with potentially differing characteristics to the modelled population.[15] The ensuing analysis indicated that use of IPC in combination with standard care could potentially afford the NHS a cost-effective intervention for hard-to-heal VLUs. The small sample sizes may have increased uncertainty around the transition probability values. Furthermore, the inherent variation in patient characteristics and clinical management between the observational study[13,14] and the THIN data set[8] would have also created some uncertainties and limitations. In particular, patients who participated in the observational study were managed by specialist clinicians at wound care centres, whereas patients in the THIN database were largely managed in the community by non-specialist nurses. Moreover, the observational study[13,14] used a range of inclusion and exclusion criteria which would have resulted in a more homogenous population than in our THIN cohort of patients who were managed in clinical practice.[8] Consequently, the model may not necessarily reflect clinical outcomes associated with managing a large cohort of patients with a hard-to-heal VLU in clinical practice in the UK. Accordingly, the results should be viewed with some caution until more data become available, which can be used to update the model, particularly the findings from a controlled study assessing differences in healing rates and HRQoL between thigh-administered IPC in addition to standard care compared with standard care alone. Nevertheless, sensitivity analysis showed that as long as the 24 weeks healing rate associated with the use of IPC plus standard care is ≥0.33 and that of standard care remains at <0.26, then including this device into a standard care protocol is likely to afford the NHS a cost-effective intervention, since the expected cost-effectiveness would be <£20,000 per QALY. Moreover, the budget impact analysis indicated that if use of IPC is stopped after 6 weeks in non-improving wounds, then using this device in combination with standard care has the potential to improve the healing rate of hard-to-heal VLUs while being cost-neutral. Since the study period was limited to 24 weeks, estimating the budget impact of IPC over a longer period would be subject to much uncertainty and be beyond the remit of this study. Nevertheless, at a time when the incidence of VLUs is rising, and the health economic burden of wounds on CCGs and Health Boards is predicted to increase,[22] this analysis would suggest that including thigh-administered IPC into a standard care protocol for hard-to-heal VLUs would potentially facilitate a decrease in the annual prevalence of these wounds for no additional cost. If IPC is to become more widely used in the management of hard-to-heal wounds, resources would have to be allocated to meet the predicted demand. This would include training clinicians in the use of this device.

To our knowledge, the present study is the first attempt to estimate the potential cost-effectiveness to the NHS of using thigh-administered IPC in the management of

VLUs. Other published studies are based on IPC administered either below the knee or to the full limb. In particular, pneumatic compression devices have been reported to afford health economic benefits in the management of chronic venous insufficiency-related lymphoedema in the US.[23,24] IPC has also been shown to afford a cost-effective method to reduce the risk of venous thromboembolism in patients undergoing surgery.[25,26]

### Study limitations

The study is subject to several other limitations. The analysis included all the costs and outcomes associated with patient management over the study period. Hence, it does not consider the potential impact of those wounds that either remained unhealed or recurred beyond the study period. The analysis only considered NHS resource use and associated costs for the 'average patient', because there were insufficient data to assess the relative cost-effectiveness of using IPC in particular sub-groups, or to stratify the analysis according to ulcer size. Similarly, the analysis was unable to consider the impact of other factors that may affect the results, such as comorbidities and underlying disease severity. Additionally, the analysis was unable to consider the level of a clinician's skills and suitability of patients to receive IPC. Patients' costs and indirect societal costs as a result of patients being absent from work were also excluded from the analysis. However, the patients in this study had a mean age >67 years, and so it is unlikely that many were in employment.

## Conclusion

Within the study's limitations, the addition of thigh-administered IPC to standard care potentially affords a cost-effective treatment to the NHS for managing hard-to-heal VLUs. However, a controlled study is required to validate the outcomes of this health economic analysis. **JWC**

**Reflective questions**

- What proportion of venous leg ulcers (VLUs) in your case load become hard-to-heal?
- How do you manage hard-to-heal VLUs?
- Do intermittent pneumatic compression (IPC) devices have a role in wound care?
- Is a better understanding of the different types of IPC and their different mechanisms of action necessary to plan effective studies?

**References**


**1** White JV, Ryjewski C. Chronic venous insufficiency. Perspect Vasc Surg Endovasc Ther 2005; 17(4):319–327. https://doi.org/10.1177/153100350501700406

**2** Guest JF, Ayoub N, McIlwraith T et al. Health economic burden that wounds impose on the National Health Service in the UK. BMJ Open 2015; 5(12):e009283. https://doi.org/10.1136/bmjopen-2015-009283

**3** Guest JF, Ayoub N, McIlwraith T et al. Health economic burden that different wound types impose on the UK's National Health Service. Int Wound J 2017; 14:322–330. https://doi.org/10.1111/iwj.12603

**4** Guest JF, Fuller GW, Vowden P. Cohort study evaluating the burden of wounds to the UK's National Health Service in 2017/2018: update from 2012/2013. BMJ Open 2020; 10:e045253. https://doi.org/10.1136/bmjopen-2020-045253

**5** Bergan JJ, Schmid-Schönbein GW, Smith PD et al. Chronic venous disease. N Engl J Med 2006; 355(5):488–498. https://doi.org/10.1056/NEJMra055289

**6** Couzan S, Leizorovicz A, Laporte S et al. A randomized double-blind trial of upward progressive versus degressive compressive stockings in patients with moderate to severe chronic venous insufficiency. J Vasc Surg 2012; 56(5):1344–1350e1. https://doi.org/10.1016/j.jvs.2012.02.060

**7** Pfisterer L, König G, Hecker M, Korff T. Pathogenesis of varicose veins: lessons from biomechanics. Vasa 2014; 43(2):88–99. https://doi.org/10.1024/0301-1526/a000335

**8** Guest JF, Fuller GW, Vowden P. Venous leg ulcer management in clinical practice in the UK: costs and outcomes. Int Wound J 2018; 15(1):29–37. https://doi.org/10.1111/iwj.12814

**9** Troxler M, Vowden K, Vowden P. Integrating adjunctive therapy into practice: the importance of recognising 'hard-to-heal' wounds. Worldwide Wounds 2006. https://tinyurl.com/sb4atky4 (accessed 18 May 2021)

**10** Ivins N, Kettley K, Staines K, Turner-Dobbin H. WoundExpress: an advanced therapy for hard-to-heal venous leg ulcers. Wounds UK 2020; 16(2):80–88. https://tinyurl.com/4sh2v9c7

**11** Chen AH, Frangos SG, Kilaru S, Sumpio BE. Intermittent pneumatic compression devices: physiological mechanisms of action. Eur J Vasc Endovasc Surg 2001; 21(5):383–392. https://doi.org/10.1053/ejvs.2001.1348

**12** Kakkos SK, Szendro G, Griffin M et al. Improved hemodynamic effectiveness and associated clinical correlations of a new intermittent pneumatic compression system in patients with chronic venous insufficiency. J Vasc Surg 2001; 34(5):915–922. https://doi.org/10.1067/mva.2001.118822

**13** Naik G, Ivins NM, Harding KG. A prospective pilot study of thigh-administered intermittent pneumatic compression in the management of hard-to-heal lower limb venous and mixed aetiology ulcers. Int Wound J 2019; 16:940–945. https://doi.org/10.1111/iwj.13125

**14** Kettley K, Turner-Dobbin H. Case series evaluating thigh administered Intermittent Pneumatic Compression (IPC) as an adjunct therapy for patients with hard to heal mixed/venous leg ulcers. Wound Care Today 2020. https://tinyurl.com/484fzd87

**15** Clegg JP, Guest JF. Modelling the cost-utility of bio electric stimulation therapy compared to standard care in the treatment of elderly patients with chronic non-healing wounds in the UK. Curr Med Res Opin 2007; 23(4):871–883. https://doi.org/10.1185/030079906X167705

**16** Gov.UK. Economic assumptions 2016/17 to 2020/21. 2016. https://tinyurl.com/5727cxbz (accessed 19 May 2021)

**17** Office for National Statistics. Clinical commissioning group population estimates (National Statistics). 2020. https://tinyurl.com/9vkx8uf4 (accessed 19 May 2021)

**18** Public Health Scotland. Population Estimates. 2020. https://tinyurl.com/34xb9mrw (accessed 19 May 2021)

**19** Stats Wales. Population estimates by local health boards and age. 2020. https://tinyurl.com/sh43sc2f (accessed 19 May 2021)

**20** Nelson EA, Hillman A, Thomas K. Intermittent pneumatic compression for treating venous leg ulcers. Cochrane Database Syst Rev 2014; (5):CD001899. https://doi.org/10.1002/14651858.CD001899.pub4

**21** Coleman S, Gorecki C, Nelson EA et al. Patient risk factors for pressure ulcer development: systematic review. Int J Nurs Stud 2013; 50(7):974–1003. https://doi.org/10.1016/j.ijnurstu.2012.11.019

**22** Guest JF, Vowden K, Vowden P. The health economic burden that acute and chronic wounds impose on an average clinical commissioning group/health board in the UK. J Wound Care 2017; 26(6):292–303. https://doi.org/10.12968/jowc.2017.26.6.292

**23** Lerman M, Gaebler JA, Hoy S et al. Health and economic benefits of advanced pneumatic compression devices in patients with phlebolymphedema. J Vasc Surg 2019; 69(2):571–580. https://doi.org/10.1016/j.jvs.2018.04.028

**24** Desai SS, Shao M; Vascular Outcomes Collaborative. Superior clinical, quality of life, functional, and health economic outcomes with pneumatic compression therapy for lymphedema. Ann Vasc Surg 2020; 63:298–306. https://doi.org/10.1016/j.avsg.2019.08.091

**25** Saunders R, Comerota A, Ozols A et al. Intermittent pneumatic compression is a cost-effective method of orthopedic postsurgical venous thromboembolism prophylaxis. Clinicoecon Outcomes Res 2018; 10:231–241. https://doi.org/10.2147/CEOR.S157306

**26** Dennis M, Sandercock P, Graham C, Forbes J. The Clots in Legs Or sTockings after Stroke (CLOTS) 3 trial: a randomised controlled trial to determine whether or not intermittent pneumatic compression reduces the risk of post-stroke deep vein thrombosis and to estimate its cost-effectiveness. Health Technol Assess 2015; 19(76):1–90. https://doi.org/10.3310/hta19760

# notes