The use of intermittent pneumatic compression of the thigh to affect arterial and venous blood flow proximal to a chronic wound site

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Abstract
Intermittent pneumatic compression of the lower limbs has been shown to have beneficial effects in patients with chronic ulceration. However, the intermittent compression cuff will normally be applied over the wound, which may produce discomfort or interfere with other treatments. Thigh-only approaches to intermittent pneumatic compression could solve this problem. This study aimed to demonstrate if such a system would have positive effects on venous and arterial blood flow distal to the compression site, but proximal to wound sites. The distal venous and arterial effects of a prototype thigh-only 3-chamber sequential intermittent pneumatic compression system were tested in 20 healthy volunteers, and 13 patients with ulcers of various aetiologies using Doppler ultrasound. The system produced hyperaemic responses in the arterial flow of both test groups. The peak venous velocity on deflation of the first and second chambers of the cuff was also greater in the patients with ulceration than in the healthy volunteers (11.6 cm/s vs 8.3 cm/s, P = .1). This work demonstrates that compression of the thigh alone can produce positive haemodynamic effects in the calves of patients with chronic wounds, and that this approach should be investigated as a therapy to improve blood flow to wound sites.

KEYWORDS
arteries, hemodynamics, intermittent pneumatic compression devices, thigh, veins

1 INTRODUCTION

Intermittent pneumatic compression (IPC) has established potential in the treatment of chronic wounds. There is evidence that the technique can improve the symptoms of arterial insufficiency, and reduce oedema. Certain types of IPC have also been shown to promote the healing of wounds, and the reduction of the associated chronic pain. Yet, these devices often apply relatively high intermittent pressure over a wound site, which may cause concern to patients and clinicians, may interfere with existing treatments, and may not always be tolerated.

The haemodynamic effects of IPC are produced by the compression of veins, which is the mechanism behind its use in deep vein thrombosis (DVT) prevention.
pressure required to compress the veins in the thigh and calf of most patients is less than 40 mm Hg. IPC at below-diastolic pressures has also been shown to induce arterial hyperaemia, although several physiological mechanisms have been proposed.11 While it is known that venous and arterial effects can be measured proximal to active IPC, it is plausible that some haemodynamic effects would be present distal to a pneumatic cuff. Therefore, if thigh-only IPC was applied to a limb, it may effect blood flow changes in the calf. A suitable thigh-only compression regime could then, based on existing evidence, promote healing in calf wounds, without compressing the wound directly, or interfering with any dressings that had been applied to that wound.

Chronic wounds have several aetiologies. The underlying condition may be deep or superficial venous insufficiency, atherosclerotic disease, diabetes mellitus, or autoimmune diseases.12,13 A therapy that is generally applicable to wounds should therefore act to reduce venous hypertension and associated oedema, but also to improve nutritional supply to the wound site. A suitable IPC system would need to promote arterial hyperaemia, in the same way as other trialled devices, but also have a sequential compression that promoted venous outflow and prevented reflux where there is valvular incompetence.

**Key Messages**

- the blood flow effects of a novel thigh-only intermittent pneumatic compression system were tested in the calf.
- the aim of the study was to demonstrate that blood flow to a wound could be improved without directly compressing the wound site.
- twenty healthy volunteers and 13 patients with various ulcers were used in this study.
- the device produced changes in calf blood flow while only compressing the thigh. There were greater increases in arterial and venous flow in the calves of patients with chronic wounds than in healthy volunteers.

The objective of this trial was to determine whether a prototype Huntleigh WoundExpress sequential thigh IPC system could increase arterial and venous blood flow velocities in the calf.

| Volunteer | Arterial % Change | Venous Peak velocity (cm/s) | Volume correlate (cm³) |
|-----------|------------------|-----------------------------|------------------------|
| 1         | +8.2             | 7.3                         | 2.7                    |
| 2         | +9.0             | 7.5                         | 2.6                    |
| 3         | −30.9            | 3.8                         | 0.7                    |
| 4         | −2.4             | 4.7                         | 1.0                    |
| 5         | −18.0            | 18.9                        | 41.9                   |
| 6         | +44.6            | 6.1                         | 4.2                    |
| 7         | −8.5             | 5.5                         | 2.3                    |
| 8         | −1.5             | 10.5                        | 7.1                    |
| 9         | +29.0            | 13.0                        | 18.4                   |
| 10        | +8.4             | 2.3                         | 0.5                    |
| 11        | −1.7             | 3.5                         | 0.5                    |
| 12        | −6.9             | 5.5                         | 1.5                    |
| 13        | −4.4             | 24.1                        | 12.2                   |
| 14        | +0.9             | 6.5                         | 4.9                    |
| 15        | −11.9            | 4.9                         | 0.8                    |
| 16        | −18.4            | 11.7                        | 18.7                   |
| 17        | −6.6             | 7.9                         | 5.5                    |
| 18        | +3.2             | 6.2                         | 2.1                    |
| 19        | −9.4             | 5.3                         | 1.6                    |
| 20        | −6.8             | 11.1                        | 6.9                    |
2 | METHODS

Twenty healthy volunteers (10 male, 10 female), and 13 patients with leg ulcers of several aetiologies (8 male, 5 female) were studied (Table 1). The mean age of the volunteers was 31 years (standard deviation 10 years, median 25 years, inter-quartile range 23-40 years), and all were asked general questions to confirm that they had no symptoms or history of vascular disease. The patients (mean age 71 years, standard deviation 11 years, median 73 years, inter-quartile range 69-77 years) were recruited from the outpatients attending a Vascular clinic at West Wales General Hospital, Carmarthen. The type of ulcer was determined by the normal assessment procedure of the clinic. Informed consent was given by each subject, and the two parts of the research were approved by the South East Wales and Dyfed Powys Local Research Ethics Committees.

A prototype Huntleigh WoundExpress thigh-length intermittent compression system that had been developed in conjunction with Huntleigh Diagnostic Products Division was applied to one leg, with the subject in the supine position. The compression cuff consisted of three chambers of equal length, which were supplied by separate inputs from the prototype pump. A series of compression cycles had been developed in preliminary tests, where one aim was to ensure that venous blood would be propelled proximally in the absence of functioning venous valves. Therefore, in those cycles the chambers inflated in a distal to proximal sequential manner, but the third (proximal) chamber would not deflate before the first (distal) chamber had begun inflation to prevent venous reflux.

Two different timings of the sequence were tested in the healthy volunteers (Figure 1), with a fixed pressure of 60 mm Hg. One cycle (cycle “2”) had a more conventional sequential timing, and the other (cycle “5”) specifically aimed to prevent reflux. The timing that achieved the most positive effect on arterial and venous blood flow was then used in the tests with patients with ulcers.

Arterial and venous blood flow velocity was measured below the level of the cuff. Arterial blood flow velocity was monitored by taping an 8-MHz flat continuous wave Doppler ultrasound transducer over the dorsalis pedis artery. This was connected to a QVL-120 (SciMed Ltd.) nonimaging spectral analysis system. The transducer casing produced a fixed Doppler angle, and time-averaged maximum velocity was recorded every 5 seconds based on the previous three cardiac cycles. A standard test comprised 3 minutes resting, 10 minutes of intermittent compression, and a further 3 minutes of resting.

Venous blood flow velocity was monitored in the posterior tibial vein with the same Doppler ultrasound system. The peak velocity, the time-averaged maximum velocity, and the duration of the phase of venous flow that occurred after the deflation of each chamber of the cuff were recorded. An approximate correlate of the volume of venous blood moved was calculated by multiplying the mean peak velocity and the mean duration of venous blood flow. The absolute volume blood flow in a vein or artery during a compression cycle cannot be measured accurately without additional continuous monitoring of the cross-sectional area of the vessel.

3 | RESULTS

3.1 | Healthy volunteers

Cycles “2” and “5” were due to be tested on 20 healthy volunteers. After seven tests, the trial was halted as it became clear that in a significant number of the volunteers were responding to the overall compression cycle phase as a single compression. This led to small, but continuous reductions in distal arterial flow velocity during the cycle, but a very large hyperaemia post-compression. The average response of the first seven volunteers is presented in Figure 2.

The seven tests indicated that cycle “5” showed a better venous response than cycle “2.” This was confirmed when the same cycles were tested on the full group of 20 volunteers. The approximate correlate of the volume of venous blood moved (multiplication of the mean peak velocity and the mean duration of venous blood flow) was multiplied by the number of cycles per 10-minute period to give values of 110 cm for cycle “2” (12 of 20 volunteers), and 204 cm for cycle “5” (20 of 20 volunteers) (medians 53 cm and 49 cm,
standard deviations 133 cm and 297 cm respectively, Mann–Whitney U, \( P = .7 \) two-tailed).

It was therefore decided that because the observed prolonged reduction in arterial flow would be inappropriate for patients with ischaemic ulcers, a new cycle would be devised based on cycle “5” and applied to all the 20 volunteers. Two-minute bursts of cycle “5” were interspersed with 2-minute rest periods. All the advantages of the venous effects were produced during the compression cycle. Significant arterial hyperaemia was provoked in the rest phases, which on average lasted throughout that phase. The average response of all the volunteers is presented in Figure 3.

If a hypothetical baseline flow is drawn between the average response of the first 3 minutes (before compression) and the final 30 seconds (after the final hyperaemic response), then the average percentage change in flow, based on the area under the curve, and assuming no change in arterial diameter, would be \(-1.20\%\). Individual responses are given in Table 1.

Venous blood flow was assessed in all the volunteers, with 10 successive measurements of increased peak venous flow velocity between compressions (Table 1). The average peak velocity following the deflation of the first and second chambers caused by the intermittent compression was 8.3 cm/s (median 6.4 cm/s, standard deviation 5.4 cm/s). 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 6.8 cm (median 2.7 cm, standard deviation 9.8 cm).

### 3.2 Patients with leg ulcers

The arterial flow velocity measurements during compression, averaged for the group, are given in Figure 4. In only 7 patients was a signal detectable in the dorsalis pedis artery (patients 1, 2, 4, 5, 8, 11, and 13), most likely because of severe calcification or distal vessel occlusion (Table 2). While the results may not reflect the group as a whole, as they are from those patients who had less severe disease in the smaller distal calf vessels, they illustrate a very clear response.
That response is similar to that observed previously in healthy volunteers, with large flow increases over baseline during whole of the pump “off” phases, with the addition of a rising baseline trend. If a hypothetical baseline flow is drawn between the average response of the first 3 minutes (before compression) and the final 30 seconds (after the final hyperaemic response), then the average percentage change in flow, based on the area under the curve, and assuming no change in arterial diameter would be +4.76%. Figure 4 shows that the duration of the hyperaemic effect was around 2 minutes, but is difficult to quantify this meaningfully with the changing baseline and the small number of patients.

Venous blood flow was assessed in all the patients, with 10 successive measurements of increased peak venous flow velocity between compressions (Table 2). The average peak velocity following the deflation of the first and second chambers caused by the intermittent compression was 11.6 cm/s, (median 7.3 cm/s, standard deviation 6.7 cm/s), which was greater than for the previous group of healthy volunteers (Mann–Whitney U, $P = .1$ two-tailed) (Figure 5). 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 (median 4.2 cm, standard deviation 8.9 cm), which was greater than for the healthy volunteers (Mann–Whitney U, $P = .3$ two-tailed).

### Table 2

Individual blood flow velocity changes for each patient, organised by ulcer aetiology

| Patient | Arterial % Change | Venous Peak velocity (cm/s) | Volume correlate (cm³) |
|---------|-------------------|-----------------------------|------------------------|
| Arterial ulcers | | | |
| 6 | No data | 14.5 | 5.8 |
| 8 | −12.66 | 20.3 | 8.6 |
| 9 | No data | 20.5 | 25.2 |
| 12 | No data | 5.8 | 2.0 |
| Venous ulcers | | | |
| 4 | −6.44 | 4.3 | 1.6 |
| 5 | +7.53 | 7.1 | 2.1 |
| 11 | +6.48 | 7.3 | 4.2 |
| Diabetic ulcers | | | |
| 1 | −2.05 | 20.3 | 27.8 |
| 7 | No data | 19.5 | 12.4 |
| Mixed ulcers | | | |
| 3 | No data | 4.0 | 0.6 |
| 10 | No data | 13.7 | 9.4 |
| Systemic Lupus Erythematosus | | | |
| 2 | +33.81 | 6.9 | 2.2 |
| 13 | +6.83 | 6.6 | 4.5 |
DISCUSSION

The results of this preliminary investigation are consistent with four propositions:

1. An intermittent pneumatic compression cuff and compression cycle can be designed that has a positive effect on both arterial and venous blood flow in the lower limb.
2. Intermittent pneumatic compression of the proximal lower limb (thigh) can have positive effects on the blood flow in the distal lower limb (calf).
3. Compression sequences designed to prevent venous reflux in the presence of valvular incompetence can be used without reducing overall arterial flow.
4. The haemodynamic response to intermittent pneumatic compression of patients with vascular disease can be equal or greater than that of healthy volunteers.

While the effect of intermittent pneumatic compression to change arterial and venous flow in the lower limbs has been investigated before, this trial was novel because it used a thigh-only cuff and measured distal effects. This investigation was limited however, and did not, for instance, measure toe pressures, tcPO2, pain levels or limb volume changes, nor was there a comparison of the effects on blood flow in the feet with conventional IPC. Continuous wave Doppler ultrasound was used because it was practically better to tape a flat probe to the limb for monitoring over the compression period; however, this did not allow imaging of the vessel, and the absolute velocities could only be calculated with assumed angles between the vessel and probe. The relatively small numbers of subjects in this trial and the heterogeneity of disease conditions of the ulcer patients also make it difficult to draw firm conclusions from these data. Detailed scans of the arteries and veins of each of the patients were not available, and therefore some differences in effect may have been caused by different underlying vascular conditions. However, if the four propositions outlined above could be substantiated through further work, and the system used in a longer-term clinical trial to assess changes in ulcer healing and symptoms, there could be the basis for a new approach to the treatment of chronic wounds. The focus of the use of this device would be to improve the general vascular health of the tissue around a wound, rather than affecting the wound directly. It would not, therefore, conflict with other topical wound treatment or local dressings.

The nature of the effects of this system on the arterial and venous flow is similar to those noted in previous research. There is hyperaemia post-compression, and increases in venous flow caused by compression. However, this compression system in unlike any used previously, and all the effects observed are distal to the cuff, rather than proximal as in previous research. The lack of an overall increase in arterial blood flow in healthy volunteers during the compression period, and the modest increase in patients is not unexpected, as the hyperaemia is effectively compensating for flow reductions during compression when outflow is prevented. The two tested groups are not comparable in age or other demographic characteristics; however, they do represent the two extremes of vascular disease, from wholly absent to severe. These results are consistent with those measured during previous research of the proximal effects of calf and thigh compression, where a greater effect in patients than in healthy volunteers was also observed.

These short-term arterial and venous flow increase are no more than would be expected from normal exercise of the limbs. However, as many patients with calf or foot ulcers will have limited mobility this device can stimulate these periodic increases in flow without any physical effort by the patient. There is the potential, then, to use IPC of the thigh to restore blood and fluid flow patterns in the limbs of chronic wound patients that are closer to those of more mobile patients, and possibly aid the healing of those wounds.

CONCLUSION

Existing IPC systems aimed at treating chronic ulceration using calf, foot/calf, or calf/thigh garments, intend to compress the site of the wound. While this research only
indicates the haemodynamic potential of a thigh-only approach, it does give some justification for continuing to evaluate using specific sequences of compression in the thigh to promote healing of wounds caused by chronic venous, arterial, and other disease. A long-term trial of the effects of a device such as the Huntleigh WoundExpress on the healing of chronic wounds could be conducted in combination with standard treatments, and as there should be no negative haemodynamic effects, it would not pose any risk to the recruited patients’ progress.

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