# Healing venous ulcers with cycloidal multidirectional vibration therapy


- **Objective:** This preliminary study combined compression bandaging with cycloidal vibration to determine whether this would enhance the rate of healing of venous leg ulceration.
- **Method:** Twenty-one patients with venous ulceration were enrolled into a 12-week trial. The vibration device was used three times daily for 30 minutes on each occasion, along with compression bandaging.
- **Results:** Ulcers of 13 patients (62%) healed within 12 weeks. The remaining eight patients completed the 12-week study with a 31–90% reduction in ulcer size. A reduction in pain was observed in 17 out of 21 patients (81%). Ultrasound measurements showed reduced fluid content in the upper dermis in patients whose ulcers had healed and in others whose ulcers were improving.
- **Conclusion:** This preliminary study shows that gentle cycloid vibration, combined with standard compression bandaging, enhances the healing rate of venous ulcers and helps to relieve pain.


- **Declaration of interest:** This study was supported by an educational grant from Vibrant Medical, UK.

venous ulceration; compression bandaging; cycloidal multidirectional vibration


Venous hypertension due to venous valvular incompetency is the major cause of leg ulceration in the UK and many other Western countries. Incompetent valves in the deep or superficial veins in the leg associated with increased venous hypertension lead to back flow into the capillaries, which become congested and permeable, allowing fluid to seep through the capillary wall into the interstitial spaces, causing oedema.[1] The microcirculation is impeded, leading to tissue deoxygenation and nutritional loss. This initiates tissue breakdown, ulceration and non-healing.[1]

Venous hypertension in ambulatory patients can be improved by compression, either with bandages or hosiery. Passive limb exercises or walking will disperse fluid in the tissues by intermittent compression, thereby channelling the fluid into the lymphatic drainage system and back into the vascular system. Limb elevation, with the patient in the supine position and the limb at heart level, also promotes venous drainage.[2,3]

Earlier studies using vibration, delivered via pads, chairs or beds, have shown benefits including tissue warming, fluid dispersal, improved microcirculation, pain relief and decreased stiffness.[4] Ryan et al.[5] found that in healthy adults there was a shift of fluid in the dermis and epidermis, indicated by non-invasive high-frequency ultrasound measurement. In the same study, using a scanning laser Doppler, which measures blood flow in the capillaries before and after cycloid vibration, the microcirculation was found to be significantly increased.

In view of Ryan et al.'s results,[5] this preliminary study set out to investigate the effects of gentle cycloid vibration combined with compression bandaging in ambulatory patients with venous ulcers.

## Literature review

Rodbard demonstrated that fluid dispersal around a leaking vessel could allow the vessel to expand.[6] Wisham et al.[7] showed that local application of cycloid vibration therapy for 20 minutes resulted in a significant rise in skin temperature of 2.2°C, indicating an increase in blood flow. They also found that increased clearance of radioactive $Na^{24}$, injected cutaneously, increased following cycloid vibration therapy.[7]

Similar observations were noted by Ryan and Salter,[8] who measured skin temperature during and after vibration therapy and observed different patterns of response, thought to be due to differences in the stiffness of the tissues and hence in the ease with which blood vessels dilate within their supporting connective tissue.

Vibration of solid elements in normal tissues compresses blood vessels and reduces blood flow, while enhancing drainage of tissue fluid into the lymphatics. Following vibration, blood vessels expand and fill the space vacated by the tissue fluid, causing the blood flow to increase temporarily.[8]

Pickup et al.[9] noted an increase in calf volume in patients with leg ulcers immediately after 30 minutes of vibration three times a day, with the volume returning to previbration values about five hours later. They hypothesised that cycloid vibration increased capillary permeability, in turn increasing tissue fluid turnover and levels of protein exudate. A slight improvement in ulcer healing was noted, with pain reducing dramatically in nine of the 12 patients, who ceased to require analgesic drugs within a week. However, Pickup et al. were unable to explain the pain reduction, which was long term.

Lieven et al.[10] found that, following vibration, the arteries and veins in mice dilated during and after


**J.M. Wilson**, RN, Clinical Research Nurse;
**Y.M. Arseculeratne**, MBBS, MPhil, Visiting Research Fellow;
**Y. Yang**, MSc, Visiting Research Fellow;
**G.W. Cherry**, DPhil (Oxon), Principal Clinical Scientific Officer;
All at Oxford Wound Healing Institute, Churchill Hospital, Oxford, UK.
Email: oxfordwound@aol.com



### References

1 Hofman, D. Oedema and the management of venous ulcers: an update on the physiology of oedema and its effects on healing in venous ulceration. J Wound Care 1998; 7: 345-334.

2 Hu, D., Phan, T.T., Cherry, G.W., Ryan, T.J. Dermal oedema assessed by high frequency ultrasound in venous leg ulcers. Br J Dermatol 1998; 138: 815-820.

3 Xia, Z., Wilson, J., Hu, D., Cherry, G.W. et al. Venous oedema assessed by echographic image analysis following leg elevation. Submitted for publication to J Wound Care.

**4** Bierman, W. Influence of cycloid vibration massage on trunk flexion. Am J Phys Med 1960; 39: 219-224.

**5** Ryan, T. J., Thoolen, M., Yang, Y. The effect of mechanical forces (vibration or external compression) on the dermal water content of the upper dermis and epidermis, assessed by high frequency ultrasound. J Tiss Viab 2001; 11: 3, 97-101.

**6** Rodbard, S. Capillary blood flow and fluid exchange regulation. Bibliotheca Anatomica 1973; 12: 366-375.

**7** Wisham, L.H., Shaanan, A., Bierman, W. The influence of vibration on temperature and on clearance of radioactive sodium in human subjects. Arch Phys Med Rehab 1956; 37: 5-10.

**8** Ryan, T.J., Salter, D. The effect of vibration on skin blood flow. Bibliotheca Anatomica 1977; 16: 180-184.

**9** Pickup, A.J., Alexander, S., Gosling, R.G. The effects of cycloid vibration on leg blood flow and ulcer pain. Paper presented at Advances in Medicine Conference, Royal Society of Medicine, 1978.

**10** Lieven, P., Leduc, A., Dewald, J. The use of multidirectional vibrations on wound healing and on the regeneration of blood and lymph vessels. In: Proceedings of the VII International Congress of Lymphology. Prague: Czechoslovak Medical Press, 1981.

**11** Cameron, J., Hofman, D., Poore, S., et al. A retrospective trial in the treatment of venous leg ulcers. Wounds 1996; 8: 95-100.

**12** Hofman, D., Ryan, T.J., Arnold, F. et al. Pain in venous leg ulcers. J Wound Care 1997; 6: 222-224.

**13** Thomson, B., Hooper, P., Powell, R. et al. Four-layer bandaging and healing rates of venous leg ulcers. J Wound Care 1996; 5: 213-216.

**14** Duby, T., Hofman, D., Cameron, J. et al. A randomized trial in the treatment of venous leg ulcers comparing short stretch bandages, four layer bandage system and a long stretch-paste bandage system. Wounds 1993; 5: 276-279.

**Fig 1. A patient trying the Vibro-Pulse pad**

treatment, but the lymphatics constricted during vibration and vasodilated after it. Surgically cut lymphatic vessels reformed significantly faster following vibration.[10]

Ryan and Salter's explanation for the effects of vibration was that it 'expedites the dispersal of tissue fluid lying between the more solid and vibrating elements of the tissues. Exercise and vibration, by aiding lymphatic pumping, cause tissue fluid pressure to fall. While vibration of the skin is in progress, the relatively stiff tissue components transmit vibration well, causing tissue fluid to be pumped into and along the lymphatics, reducing tissue pressure, at the same time as blood vessels are compressed and blood flow is reduced. When vibration stops the blood vessels are able to expand, the vibration having decreased both pressure and total volume of the tissue by decreasing the fluid content of the colloidal gel of the dermis.'[8]

## Methods

Twenty-one patients (six male, 15 female), with venous ulceration documented by light reflective rheography were enrolled into our 12-week study. Their ages ranged from 51 to 93 years (mean: 74). They had an ulcer duration of 1–48 months (mean: 11.1), with an initial ulcer size of 0.75–28.75cm$^2$ (mean: 6.2cm$^2$).

The patients all had venous pathology and an ankle brachial pressure index (APBI) greater than 0.8, were able to maintain the treatment regimen themselves and gave informed written consent. Patients with acute infection or cellulitis, congestive heart failure, active arthritis or recent hip replacement were excluded as they are not suitable for vibration therapy.

Prior approval was obtained from the Central Oxford Research Ethics Committee (COREC). Following enrolment, patients attended clinic twice a week for dressing changes, or the research nurse visited the patient at home.

Doppler ultrasound and light reflective rheography were carried out to measure ABPI and venous refilling time respectively, in order to confirm the aetiology. A history of the ulceration, including the duration and the compression used, was recorded. Setopress (Seton Healthcare) compression bandaging was applied following the dressing change to establish the degree of comfort and wear time. Setopress was chosen because it is comparable to the four-layer system in performance, safety and cost.[11]

Vibro-Pulse therapy (Vibrant Medical, Sheffield) has a three-dimensional cycloid action that produces a gentle vibration. The pad is placed under the lower leg, which is stabilised with a padded compression strap (Fig 1). The 24-volt device is connected to a transformer and has a hand-held control panel. Vibro-Pulse switches off automatically after a 30-minute treatment period. Patients were advised to use the Vibro-Pulse on their bed at home to promote venous drainage and for added safety.

## Study protocol

Vibro-Pulse was used three times daily in each patient's home for 30 minutes, with a minimum of three hours between treatments. Patients completed a treatment form, stating the time and duration of each treatment. The form also included a comments section.

At the twice-weekly dressing change, the leg was washed in warm tap water, dried and moisturised with 50% white soft paraffin and 50% liquid paraffin. A knitted viscose primary non-adherent dressing (Johnson and Johnson) was used as a primary dressing with a pad to absorb exudate. Tubifast (SSL International) was applied to the lower leg to protect the skin. Soffban (BSN Medical), a cotton wool bandage, was applied from the base of the toes to the tibial tuberosity to protect the malleoli and tibial crest, followed by the Setopress compression bandage.

## Outcome measures

The following assessments were undertaken weekly, either at the clinic or in the patient's home:

- Ulcer area: determined by tracing the circumference of the wound and monitored by photography
- Leg circumference for calculating leg volume: measurements at 4cm intervals from the malleoli to the tibial tuberosity were made and computer analysis was carried out using Limb Volume Calculator IBM version J
- Quality of life assessments (pain, odour, exudate).

Pain was assessed by the patient using a visual analogue scale,[12] where 0 = none; 1 = mild; 2 = uncomfortable; 3 = distressing; 4 = horrible; 5 = excruciating.

The amount of exudate was established by the amount of strikethrough to the non-adherent dressing, pad or bandage (none, mild, moderate or heavy). Odour was determined by both the patient's and the research nurse's perception on a scale of none, mild, moderate, offensive.

At four-weekly intervals, Dermascan Ultrasound was used to determine tissue hydration levels and the dermal structure on both lower legs. Predetermined areas at three points of each leg — lower (ankle), middle (calf) and upper (below knee) — were documented at the first scan to ensure the same area was scanned in subsequent visits. Analysis of pre- and post-study ultrasound results was used to assess morphological changes, including tissue oedema. The pre-treatment scan served as the control to monitor oedema.

## Results

All 21 patients participated in this study. Thirteen (62%) healed completely over a mean duration of seven weeks (range: 4–12). The average size of these healed ulcers at the start of the study was 3.6cm$^2$ (range: 0.75–7.75cm$^2$) and the mean duration was eight months (range: 1–48).

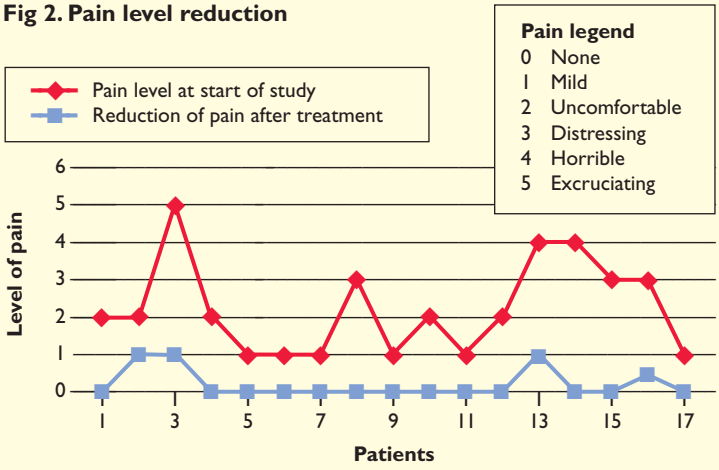
Of the eight patients who had not healed by 12 weeks, three had leg ulcers greater than 10cm$^2$ (mean: 18.25cm$^2$; range 12.5–28.75cm$^2$) at the start of the study, with a mean duration of 29 months (range: 4–48). These patients showed a reduction in ulcer size of 63–65% at the end of the study. The other five patients had ulcers less than 10cm$^2$ (mean size: 6.55cm$^2$; range: 2–9cm$^2$) and a mean duration of eight months (range: 2–24). They showed a reduction in ulcer size of 31–90% at the end of the study.

### Quality of life assessments

All patients managed their therapy at home and found it pleasant, relaxing and compatible with their lifestyle. Three patients said it helped their mobility.

- **Pain** There was a reduction in pain in 17 of the 18 patients (94%) who were experiencing pain at the start of the study (Fig 2). Six patients with 'mild' pain and four with 'uncomfortable' pain reduced to 'no pain'. One patient with 'horrible' pain and one patient with 'excruciating' pain reduced to 'mild' pain. Three patients had no pain throughout the study and one patient's pain increased from 'distressing' to 'horrible'.
- **Exudate** There was a reduction in exudate in 11 of the 21 patients (52%). Fourteen patients experienced no wound odour during treatment, and in four patients the wound odour resolved. In the remaining three patients wound odour fluctuated between none, mild or moderate.
- **Oedema reduction** Computer analysis of the circumferential measurements of the lower leg showed up to a 15% reduction in limb volumes (Fig 3). This gross reduction correlated with the ultrasound analysis, which showed a reduction of fluid content in the upper dermis of patients who had healed and in those whose ulcers were reducing in size.

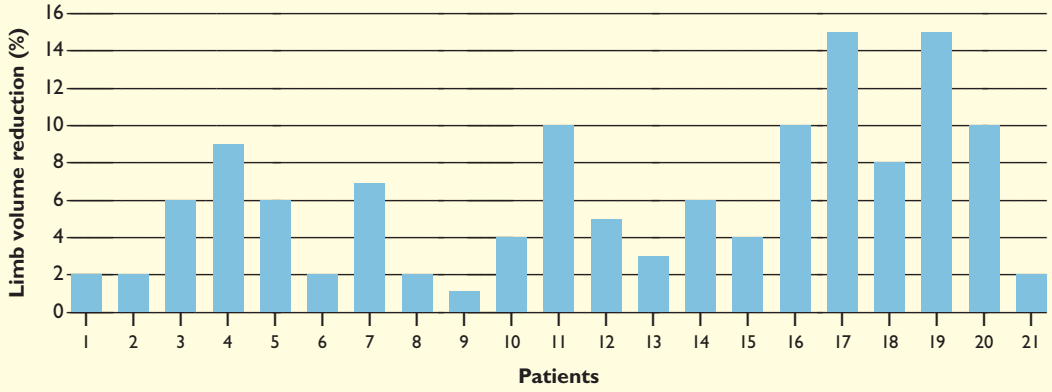
**Fig 2. Pain level reduction**




## Discussion

Duration and ulcer size are well-known factors associated with delayed healing. In this study 62% of the patients healed within 12 weeks with the com-

**Fig 3. Percentage of limb volume reduction**



### Box 1. Case study

Mrs W is an 83-year-old woman with a long history of bilateral venous ulceration. She underwent varicose vein stripping in 1982 and has psoriasis. The ABPI on her left leg was >1.0. The superficial ulcer on the left medial was 8.75cm$^2$. She had daily dressings (alginate) for exudate control and compression.

Her pain score was 4 (scale 0–5) or 'horrible'. The skin was extremely fragile with pustular dermatosis, for which Trimovate (GlaxoWellcome) was prescribed. Patch testing had shown allergies to lanolin, hydrocortisone, colophony and parabens.

Dressings were reduced to three times weekly with a non-adherent primary dressing, pad, Soffban and Setopress. By week four her pain had reduced to level 1 (mild) and her mobility had improved. Exudate was more manageable and the ulcer was reducing in size. Dermascan ultrasound showed a reduction in oedema. At the end of the 12-week study the ulcer had reduced by 65% to 10cm$^2$.

**The leg ulcer's initial size was 28.75cm$^2$**

**By week 12 the ulcer had reduced in size by 65% to 10cm$^2$**

### Box 2. Summary of the main points

This preliminary study aimed to discover the effect of combining two therapies — compression bandaging and cycloidal vibration using a device called the Vibro-Pulse pad — on healing rates of venous leg ulcers

Twenty-one patients with venous ulcers joined a 12-week trial. They used the vibration device three times a day, at home and kept records of the effect on pain, mobility and ulcer healing rate

While figures differ, one study has shown a 40% healing rate at 12 weeks for compression bandaging and another a 44% healing rate for an arm of a randomised controlled trial treated with four-stretch bandaging

In this study 13 patients (62%) healed within 12 weeks and the other eight had a 31–90% reduction in ulcer size. In 17 out of 18 patients (81%) pain was reduced

A randomised, prospective controlled study with more patients and using the vibration device in mixed aetiology ulcers and lymphoedema is proposed

bined compression and cycloid vibration therapy. Before enrolment 13 patients (62%) had been wearing class III compression, either Tensopress (Smith and Nephew) or Setopress, one patient had used short-stretch bandaging and seven patients had been wearing Tubigrip.

The percentage of patients with venous ulcers that heal with compression bandaging, specifically the four-layer system, has varied in the different studies published. However, a community study of 514 venous leg ulcers found a 40% healing rate at 12 weeks.[13] In a randomised prospective trial involving 67 patients the healing rate for subjects in the four-layer bandaging arm was 44%.[14] The percentage of patients who healed in the present study was 62%.

We observed up to 15% reduction in leg volume by the end of the 12-week study. This could be attributed to the combination of cycloidal vibration therapy and compression bandaging. Cycloidal vibration therapy has been shown to produce fluid shift at the tissue level and to improve the microcirculation, even in people without venous disease or being treated with compression therapy.

The most striking feature of this combined therapy was the improvement in quality of life, particularly with respect to pain relief. This was of clinical significance, with 81% of patients reporting either complete absence or a reduction in pain. A number of patients with restricted mobility reported an improvement during the study.

**Acknowledgement**
**We would like to pay tribute to Peter Nielsen who died recently. He was the inspiration for and instigator of the present study and of research in this field over the years**

### The psychological impact

We would like to emphasise the psychological impact of the vibration treatment on the patients due to their active participation in their treatment. This was further reinforced by showing patients the computer-generated graphs of the fluid lost from the treated leg over a certain time period. They were also shown photographs of the improvement in healing. Self-empowerment, coupled with improvements in the parameters used to assess quality of life, played a significant role in the patients' well-being, which further enhanced the healing process.

### Cost analysis

Although this preliminary study was not initially designed to measure cost benefits, early-stage cost analysis indicates that the enhanced healing of the chronic ulcers could result in cost savings in nursing time and dressings.

For example, a patient with a venous ulcer had been treated with high-compression bandaging for four months before entering the study, with dressing changes twice a week. The cost of nursing time was £730 and that of bandaging and dressing was £70 — a total of £800 for four months. At the start of Vibro-Pulse therapy the ulcer was 7cm$^2$. It healed in five weeks, costing £165 in nursing time and £20.60 in bandaging and dressings. The Vibro-Pulse pad rental for four months was £149.13 — total cost to heal £334.73.

## Conclusion

This preliminary study has shown that cycloid vibration combined with compression bandaging improved healing of venous ulcers and enhanced quality of life, particularly in relation to pain relief. A randomised prospective controlled study and further research into Vibro-Pulse on mixed aetiology ulcers and lymphoedema is proposed. ■