

Home use of impulse compression of the foot and compression stockings in the treatment of chronic venous insufficiency

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Purpose: The use of intermittent pneumatic compression, in addition to elastic bandages or stockings, accelerates the healing of leg ulcers in patients with severe chronic venous insufficiency (CVI). There is recent evidence that impulse compression of the plantar venous plexus reduces post-traumatic ankle swelling and prevents postoperative venous thromboembolism. The purpose of this study was to evaluate the clinical and hemodynamic responses after home use of impulse foot compression for 3 months in patients already using therapeutic compression stockings for the management of CVI.

Methods: Twelve extremities from 9 patients with documented CVI, class 4 to 5 according to the Clinical, Etiology, Anatomy, Pathophysiology classification system, were included in this prospective cohort study. All patients were instructed to use a foot pump device at home for 2 hours a day for 3 months in addition to therapeutic compression stockings (30–40 mm Hg) worn during the day. The device was set to three cycles (3 seconds) of compression (120 mm Hg) per minute. A clinical scoring system was completed before foot compression and 1, 2, and 3 months thereafter. In addition, all patients underwent air plethysmography studies at the same time intervals, including venous volume, venous filling index, ejection fraction, and residual volume fraction.

Results: Patients reported significant improvement in their scores for swelling ($P < .05$) and pain ($P < .04$). Air plethysmography showed a reduction in venous volume and venous filling index, although these differences were not significant. Ejection fraction remained unchanged and residual volume fraction was significantly reduced ($P < .05$) compared with baseline. The foot compression devices were well tolerated by all the patients in the study.

Conclusions: The use of home foot impulse compression plus elastic stockings significantly reduced the residual volume fraction as measured by air-plethysmography in a group of patients with severe CVI. This favorable hemodynamic response could, in part, explain the clinical improvement achieved by this combined treatment. However, this represents a preliminary pilot study that needs to be confirmed in future randomized controlled studies with more patients included. (J Vasc Surg 2001;34:805-11.)

Chronic venous insufficiency (CVI) is a widespread and debilitating problem affecting approximately 5 to 7 million persons in the United States, in 400,000 to 500,000 of whom venous leg ulcers will develop.¹ In the United Kingdom, the prevalence of leg ulceration is close to 0.4% in persons older than 40 years, and more than 90% of these ulcers are caused by venous disease.²

Different types of compression therapy have been introduced for the management of CVI, from simple bandages with uniform compression to modern graduated elastic stockings. Compression is directed to controlling edema and reducing ambulatory venous pressure (AVP) and by doing so, improving calf-muscle pump function³

and relieving patient symptoms.⁴ Several studies have demonstrated that external pneumatic compression of the legs, in addition to stockings or bandages, improves the healing of venous ulcers⁵⁻¹⁰ and alleviates symptoms in patients with CVI without ulcers.¹¹⁻¹³

A physiologic venous pump in the foot, consisting of the venae comitantes of the lateral plantar artery, has been described by Gardner and Fox¹⁴ using video phlebography. Subsequently, devices have been developed that inflate rapidly, compressing and flattening the foot and inducing a prompt emptying of the venous foot blood into the veins of the leg. This high-pressure impulse compression of the foot increases the popliteal and femoral vein blood velocity in normal volunteers.¹⁵⁻¹⁸ In addition, foot compression reduces venous pressure¹⁹ and calf volume measured by strain gauge plethysmography²⁰ in healthy volunteers. Impulse foot compression increases deep vein blood flow velocity^{21,22} and reduces vein pressure in patients with CVI.²³ These have been investigated for the prevention of postoperative venous thromboembolism in some orthopedic patients, with controversial results.²⁴⁻²⁹ They have been shown to reduce post-traumatic³⁰ and postoperative swelling.³¹ Besides, rapid impulse compression of the foot,³² calf,³³ or foot and calf^{34,35} may be of benefit to patients with severe peripheral artery disease

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because these methods improve popliteal artery blood flow,^{33,36} skin perfusion,³⁷ and ankle brachial pressure index.³²

Air plethysmography (APG) has become a valuable tool for noninvasive and quantifiable assessment of several venous hemodynamic parameters, including calf venous volume, venous reflux, and calf pumping function, providing global information on venous function.^{38,39} This test has been used to evaluate the results of venous surgery⁴⁰⁻⁴³ and to assess the hemodynamic effects of elastic compression stockings.^{3,38} The current study was conducted to assess the clinical and hemodynamic effects of the home use of impulse foot compression and therapeutic compression stockings in the management of severe CVI.

METHODS

A group of consecutive patients with severe chronic venous disease, class 4 to 5 of the Clinical, Etiology, Anatomy, Pathophysiology classification of CVI, developed in 1994 in Maui, Hawaii, by an international consensus conference under the auspices of the American Venous Forum and accepted by the Ad Hoc Committee on Reporting Standards of the Joint Council of the Society for Vascular Surgery and the North American Society for Cardiovascular Surgery was eligible to participate in the study.⁴⁴ Patients were excluded from the study if they had active ulcers in the legs or feet or presented with severe peripheral artery disease with ankle-brachial index of 0.6 or less. Other criteria for exclusion were acute deep vein thrombosis, congestive heart failure, pregnancy, and cellulitis.

Nine patients (three women, six men), with an average age of 47.5 years (range, 38-62), attending the authors' vascular laboratories for venous assessment were studied after their informed consent was obtained. All patients had been using 30-mmHg to 40-mmHg compression elastic stockings for at least 3 months and had severe CVI as demonstrated by physical exam (Clinical, Etiology, Anatomy, Pathophysiology classification class 4 or 5), abnormal photoplethysmography, and venous reflux documented by duplex scanning. Three patients had CVI affecting both lower extremities; therefore, 12 limbs were included in the study. There were seven limbs with previous deep vein thrombosis proximal to the popliteal vein at the knee level and with evidence of recanalization based on the duplex scan. Regarding the clinical severity, seven limbs were class 4 (pigmentation, venous eczema, or lipodermatosclerosis), and the remaining were class 5 (skin changes with healed ulceration).

After the initial interview and physical exam, patients underwent venous duplex scanning and photoplethysmography to document the distribution and involvement of their CVI. At this initial visit, patients responded to a clinical scoring questionnaire with a five-point scale (1 = minimal problem and 5 = maximal problem) that was used to quantify the symptoms of swelling, pain, skin discoloration, cosmetic problems, decreased activity tolerance, depression, and sleep problems caused by the disease. In the follow-up

questionnaires, patients were also asked to rate any new numbness, sweating, itching, or pain associated with the use of stockings or compression foot pump (Appendix). All questionnaires were completed on site at each visit to the vascular laboratory with the assistance of a nurse or physician before foot compression and during follow-up visits. Patients were unaware of their previous answers.

All patients underwent an initial assessment with an air plethysmograph (APG-1000, ACI Medical, Sun Valley, Calif) as described by Christopoulos et al.³⁸ The following indices were calculated from the recording chart: venous volume, venous filling index (VFI), ejection fraction (EF), and residual volume fraction (RVF). Patients did not wear stockings during the APG exam, and no tourniquets were used. After this initial visit, patients underwent follow-up physical exams, clinical score questionnaire, and APG examinations 1, 2, and 3 months thereafter.

All patients had their leg circumferences measured at the ankle and calf and were instructed to wear the appropriate size calf-length 30-mmHg to 40-mmHg elastic compression stockings (MediUSA, Arlington Heights, Ill). In addition, patients received training in the home use of an impulse foot pump (ActOne, New Dimensions in Medicine, Dayton, Ohio). This device consists of a programmable air compressor unit that insufflates air intermittently into a slipper that is tightly applied to the sole of the foot and secured with hook and loop fasteners. The slipper incorporates a rigid sole and an inflatable, dual-chamber bladder system, which applies a differential of pressure to chamber one, the plantar chamber, applying pressure along the entire length of the plantar area, and chamber two, which applies graded pressure to the dorsal region of the foot. The devices were programmed to apply a rapid (0.4 seconds) impulse compression (120 mmHg) for 3 seconds with a frequency of three cycles of compression per minute. Patients were asked to use this device at home 2 hours a day with the stocking on every day for 3 months and to keep a record book regarding the number of hours of foot pump use. To improve the priming of the plantar veins between the compression cycles, patients were asked to sit up in bed or on a couch with their torso elevated at least 45° and legs horizontal while using the foot pump.

Statistical analysis of data consisted of the Wilcoxon matched-pairs ranks test to compare the results of the clinical score after foot compression therapy with baseline score. A two-sided paired *t* test was used for comparison of APG results before and after compression treatment. Descriptors used are median and 25% to 75% interquartile ranges for the results of the clinical score, which were not normally distributed, and mean and standard deviation for the APG results. Differences were considered significant if the *P* value was less than .05. Analysis was carried out using the program SigmaStat (Jandel Scientific).

RESULTS

Patients used the foot pump 2.5 hours each day, usually in the evening, for an average of 5.5 days per week.

Table I. Clinical scores before and during treatment with foot pump*

Symptom	Baseline	1 mo	2 mo	3 mo
Swelling	5 (4-5)	3 (2-4)	2 (2-3)†	3 (2-3)‡
Pain	4 (3-4.5)	2 (1.75-3)†	2 (1.5-2)†	2 (1-2.75)†
Discoloration	3.5 (2-5)	3 (1-3)	3 (2-3.5)	2 (2-2.75)
Cosmesis	2.5 (1-4)	3 (2-5)	2.5 (1-4)	4 (2.5-5)
Decreased activity	3.5 (1-4.5)	2 (1-3.25)	1.5 (1-2)†	2 (1.25-4)
Depression	2.5 (1-4.5)	1 (1-4)	1 (1-3)	1 (1-2.75)
Sleep problems	1.5 (1-3)	1 (1-1)	1 (1-1)	1 (1-1)

*Values given as mean (25%-75% interquartile range). Wilcoxon rank sum test at 1, 2, and 3 months after treatment compared with baseline.

† $P < .05$.

‡ $P = .01$.

Impulse compression was well tolerated considering that only two patients had increased sweating in the foot and one patient felt some numbness in the heel during the compression sessions. However, these patients did not discontinue the use of the foot pump as a result of these problems. Most patients used the foot pump in the evening, and they did not experience any limitation to their normal activity as a result of the use of the foot pump.

The results of the clinical questionnaire are presented in Table I. There was a significant reduction in the severity score for swelling ($P < .05$) and pain ($P < .05$) throughout the treatment period and a reduction in the score for reduced activity that was significant in the second-month survey ($P < .05$). The average total severity score, obtained by adding the individual scores given by patients to each symptom, was reduced from 21.5 before treatment to 16.8 after 1 month ($P = .003$), 14.4 after 2 months ($P = .002$), and 14.4 ($P = .001$) after 3 months of treatment. No patient reported a worsening in his or her condition as a result of the compression therapy.

The results of the baseline and follow-up APG examinations are detailed in Table II. The average venous volume decreased as a result of the use of stockings and foot compression, but differences were not statistically significant. Patients were not wearing the stockings during the APG exam.

The baseline average VFI was more than twice the VFI in normal limbs, which is 1.7 mL/s according to Christopoulos et al.³⁸ This parameter remained without significant changes during the compression therapy.

The average EF, which represents the proportion between the ejected volume after a single tip-toe movement and the venous volume, was 54% before compression treatment, and 6 of the 12 limbs had an EF of $<50\%$. Healthy persons without CVI have an EF $<60\%$.³⁸ There was a slight increase in the EF, but this was nonsignificant during treatment.

RVF is the proportion between the residual volume after 10 tip-toe movements and total venous volume. The normal RVF is $<35\%$. In our patients, RVF was 57.6% before treatment and decreased significantly to normal values during the three APG examinations ($P = .01$). There were not statistically significant differences in the APG results between patients with or without previous

venous thromboembolism, and APG parameters were not significantly different in patients with CVI class 4 or 5.

DISCUSSION

Treatment of patients with severe CVI relies on the use of compression therapy, provided by means of elastic stockings or bandages. This treatment is not tolerated by some patients, leading to irregular use of the compression support; as a result of this lack of compliance, leg ulcers develop.

During the past 10 years there have been some favorable reports on the use of external pneumatic compression of the legs for the management of severe CVI, as an adjunct to the use of elastic stockings.⁵⁻¹² We conducted a previous study in a group of patients with CVI who were treated at home with external pneumatic compression and elastic stockings.¹³ There was a dramatic clinical improvement and a significant increase in the EF, as detected by APG. However we did not find significant changes in RVF as we did in the current study using an impulse foot pump.

There is limited clinical experience with the use of impulse compression of the foot in patients with CVI. McMullin et al²³ reported that the application of a foot pump to patients with CVI who were standing resulted in a reduction in the AVP that paralleled the pressure reduction found during walking. More recently, Malone et al²² compared the influence of different compression devices on the popliteal and femoral blood velocity. They found that high-pressure, rapid inflation of the foot produced higher blood velocities than standard calf compression in healthy volunteers and, to a lesser degree, in patients with post-thrombotic syndrome.

Patients remained sitting with their legs raised during foot compression, instead of lying down, to obtain good priming of the plantar veins.^{22,30} We have also found higher blood velocity in the popliteal and femoral veins during foot compression in a reverse Trendelenburg position than in the supine position.¹⁸ Similar results have been reported by Abu-Own et al,²¹ who showed higher peak-flow rates in the sitting position than in the supine. On the contrary, Killewich et al¹⁷ found a similar increase in the maximum venous velocity induced by foot compression with the patient in the supine position compared with the 15-degree to 20-degree reverse Trendelenburg

Table II. APG results before and after treatment with elastic stockings and foot pump (mean \pm SD)

APG parameter	Baseline	1 mo	2 mo	3 mo
Venous volume (mL)	133 \pm 73	115 \pm 63	115 \pm 64	106 \pm 57
VFI (mL/s)	4.4 \pm 3	3.9 \pm 2.5	4.1 \pm 2.7	3.8 \pm 2.8
EF (%)	54 \pm 23	60 \pm 18	58 \pm 13	58 \pm 6
RVF (%)	58 \pm 33	24 \pm 14*	33 \pm 21*	29 \pm 18*

* $P < .05$.Paired t test compared to baseline.

position. The foot pump protocol used by us, consisting of three compression cycles per minute with a pressure of 120 mmHg, is one of the most effective in reducing venous pressure according to Delis et al.²⁰

Our results indicate a significant reduction in the score given by patients to swelling and pain after use of the foot pump. Yet, this is a rather subjective opinion given by patients, probably biased toward any new treatment modality for their chronic disease. APG has the advantage of being noninvasive and quantifiable. Furthermore, APG provides a number of parameters of global venous function, such as calf venous volume, reflux, and pumping function related to the pathophysiology of CVI.⁴⁵

A recent study by Yang et al⁴⁶ has questioned the reproducibility of APG; however, Christopoulos et al³⁸ reported good reproducibility of APG in healthy volunteers and patients with CVI. Other investigators have evaluated the role of APG in monitoring the results of venous surgery and demonstrated a significant improvement in most APG parameters postoperatively.^{40,42,43} A normal postoperative VFI predicted a good clinical outcome.⁴³

Christopoulos et al³⁸ found that stockings improve the EF and reduce the reflux, expressed by the VFI, in the calf. It is important to note that patients had the stockings on during the APG testing.³ In our aforementioned previous study with the use of home external pneumatic compression, we also found a reduction in the EF, but our patients did not wear stockings during the APG study.¹³ In our current study using stockings and the foot pump, patients did not wear stockings during the APG exam.

The EF did not increase during foot pump treatment as it did with external pneumatic compression of the calf.¹³ Yet, we were not expecting such a dramatic and sustained reduction in RVF to normal values throughout the foot pump compression 3-month period. This is an important finding because RVF provides a good estimate of the severity of calf pump dysfunction and tends to be higher in patients with severe CVI.^{47,48} Similarly, patients with leg ulcers usually have higher RVF values.^{49,50} As mentioned before, the reduction in AVP produced during the application of an impulse foot pump parallels the pressure drop produced by walking.²⁴ Therefore, when the calf pump function is poor, as in our patients, the use of foot impulse compression improves venous emptying. This could explain the RVF reduction found in our study.

Christopoulos et al³⁹ and others⁵¹ have reported cor-

relation between RVF and AVP, the gold standard of venous testing. On the contrary, Payne et al⁵² reported a poor correlation between AVP and RVF.

We have not found a significant reduction in the VFI as a result of the foot pump treatment, but we were not expecting this to occur because our treatment was not specifically intended to correct reflux. The mean VFI found (4.4 mL/s) was surprisingly low for patients with CVI, although it was twice the normal value (1.7 mL/s) reported by Christopoulos et al.³⁸ Other investigators have also reported low VFI values in advanced CVI patients.^{49,53} Araki et al⁵⁰ found similar VFI results in patients with moderate and advanced CVI. There was a mild reduction in the venous volume, although it was not significant. Patients were tested with APG several hours after discontinuing the use of the foot pump. Probably, these differences will become significant with a larger number of patients in a further study measuring venous volume at different intervals after the use of the pump with and without stockings.

Although elastic stockings and external pneumatic compression of the calf do have an additive effect on the blood flow velocity in the femoral vein according to Keith et al,⁵⁴ other investigators have found that the use of the foot pump alone produces an increase in the calf volume that is mitigated by the simultaneous use of stockings and the foot pump.²¹ We did not use tourniquets during the APG exam because they have been found to be unreliable predictors of deep or perforator incompetence by many investigators and almost abandoned during APG testing.^{45,55,56}

External pneumatic compression of the leg improves vasomotor activity in the skin of patients with venous hypertension⁵⁷ and may stimulate a fibrinolytic response in patients with CVI.^{12,58} More recently, impulse foot compression has been found to improve venous hemodynamics in patients with CVI and post-thrombotic syndrome.^{22,23} In addition, rapid impulse pneumatic compression of the foot, calf, or foot and calf increases the arteriovenous gradient as a result of venous emptying, improving arterial inflow to the foot.^{32,33,35} All of these mechanisms of action could help us to understand the favorable response of our patients to elastic stockings and foot pump compression. However, this is a preliminary report with encouraging results, but further comparative studies including a larger number of patients should be conducted to establish the best therapeutic regimen.

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NAME..... AGE.....
 ADDRESS.....
 NUMBER OF WEEKS USING SGPC..... NUMBER OF DAYS/WEEK.... NUMBER OF HOURS/DAY.....

SCORING SYSTEM FOR THE EVALUATION OF FP

Please, assign a rating to the following symptoms and signs, before and after treatment with the home foot pump (1 means minimal or no problem, 5 means a major problem)

Clinical problem	Score before FP	Score after FP
Swelling of the leg	1 2 3 4 5	1 2 3 4 5
Discomfort or pain	1 2 3 4 5	1 2 3 4 5
Discoloration of the skin	1 2 3 4 5	1 2 3 4 5
Cosmetic problems	1 2 3 4 5	1 2 3 4 5
Decreased activity tolerance	1 2 3 4 5	1 2 3 4 5
Depression	1 2 3 4 5	1 2 3 4 5
Sleep problems	1 2 3 4 5	1 2 3 4 5

Please, describe any problems you had with the stockings or compression devices using the same 1-5 rating system

Problem	Score after foot pump
Numbness	1 2 3 4 5
Sweating	1 2 3 4 5
Itching	1 2 3 4 5
Pain	1 2 3 4 5

DISCUSSION

Dr Lois Killewich (Galveston, Tex). Good morning, ladies and gentlemen, Dr Comerota, Professor Burnand.

Dr Caprini and his colleagues have conducted an interesting study of the benefits of home therapy with the pneumatic compression pump for chronic venous insufficiency. Nine patients with 12 extremities with class 3 to 5 chronic venous insufficiency were treated with compression stockings and a foot pump for 3 months. Patients were instructed to use the pump 2½ hours per day. The effects were assessed by completion of the survey of clinical outcomes and measurement of venous physiology by air plethysmography. Following the 3-month pumping period, as you have just heard, patients reported less swelling and pain, and residual venous fraction in the affected limb measured by APG was improved.

These findings are important for several reasons. First, in my mind most importantly, in this era of managed health care, we as physicians are being pressured to provide more care to patients in their homes. As Dr Rooke said yesterday, the days of treating lymphedema by putting patients in a bed in a hospital for 3 to 5 days are over. Similarly, the days of treating venous stasis disease by elevation in a hospital bed are also gone. Putting patients in bed at home with their legs elevated is not feasible if we are going to keep them productive members of society. Thus, a method which allows them to continue normal activities while controlling or improving their symptoms is useful and relevant.

Secondly, this study focuses on a method for maintenance therapy for chronic venous insufficiency. I should just point out that too often we as surgeons forget that an operation is really only successful if long-term improvement in quality of life is achieved.

Finally, Dr Caprini and his colleagues use not only a clinical survey which is by definition somewhat subjective but also an objective method, APG, to quantify outcomes. They found that the residual volume fraction, which correlates with measurements of ambulatory venous pressure, was improved by the 3 months of therapy. Many of the methods which have been used to treat venous insufficiency have been shown to provide subjective improvement, but few improve the underlying physiologic abnormalities.

As the authors point out in their manuscript, which they kindly provided to me in advance of the meeting, this study is preliminary and as such it is imperfect in some ways. The number of subjects is quite small. The study was not randomized, and it is possible that the benefits demonstrated from foot pumping would have been present if the patients had been treated only with compression stockings. Furthermore, compliance is always an issue with home therapy, and no mention is made in the manuscript as to how compliance with the foot pump was achieved. Despite these limitations, the objectives and findings are germane, and I hope that the authors plan to continue this line of research.

I have the following questions: The authors state that there were seven limbs with previously documented proximal deep vein thrombosis with evidence of partial recanalization by duplex scan. Was there any correlation between the degree of improvement provided by the foot pump and the presence of residual thrombus? Did patients with residual thrombus have a worse outcome?

Secondly, were any measures used to ensure that patients complied with the guidelines for use of the foot pump and compression stockings? For example, were phone calls made to the patients on a weekly or biweekly basis, or were they seen in clinic frequently?

And finally, have the authors considered the use of this device for healing of venous stasis ulceration?

Thank you very much.

Dr Joseph A. Caprini. First of all, Lois, I would like to thank you for a wonderful and very kind discussion. It is indeed a preliminary study. We need many more patients in this study—there is no question about it—in order to make sure that we answer some of the variables. These patients were all patients that had been treated for at least a year, and we did not make that clear in the manuscript. That is one of our many shortcomings. They had gotten what we felt was the maximum benefit from the stockings, and that is why they were considered for this study. It is very proper, now that we have begun to show that there is something—and I was very excited because I had a subjective and an objective measure that sort of agreed with my clinical bias based on testimonial, so it all fit together. I grant you now that we need to proceed with a much more sophisticated study.

Very good question about the degree of venous obstruction. The numbers are small and I did not take a careful look at that parameter in this particular study.

Now as to compliance, the single most important problem with pneumatic compression, whatever kind it is, is of course compliance and so true here. In the Spanish campus we watched them because they came into clinic which we think is probably a good way to do this, where they come into clinic and then you can actually treat them. They do not need to take any equipment home. There is a nurse there if there is a problem and so forth. Maybe they can combine it with shopping and so forth. But anyway, half of the patients, we knew their compliance. The other half of the patients, they were to keep a log. We did make in some cases daily phone calls in the beginning, but of course we have no ironclad way to document compliance. I have suggested to the companies that we put a device in the machine that will count only when the machine is on and in use and it is getting feedback pressures from the patient, so I think that is a possible improvement in the situation.

Again, it is a great honor to be able to present this and also to have the discussion by Lois. Thank you again very much. We will go back and try harder in the future to expand this study. Thank you very much.