Improvement of Venous Pumping Function by Double Progressive Compression Stockings: Higher Pressure Over the Calf is More Important Than a Graduated Pressure Profile

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WHAT THIS PAPER ADDS
So-called progressive compression devices can improve impaired calf pump function of patients with venous disease restoring this to the normal range. Maintaining the calf pressure and increasing the ankle pressure did not further improve the venous pump function. Such progressive pressure gradient devices are not available on the market, but could act as effective, self-applied compression devices, improving calf pump function to the same extent as an inelastic bandage which is more difficult to apply, almost always requiring assistance from an expert nurse or doctor.

Background: Previous studies have shown that so-called progressive elastic compression stockings (PECS) with a negative pressure gradient have a more pronounced effect on venous pump function than conventional, graduated stockings. The aim of this study was to investigate the effect of higher graduated and non-graduated pressures on the venous calf pump in patients with venous disease.

Methods: The ejection fraction (EF) of the calf pump was measured by plethysmography under a standardized walking test in 20 patients suffering from chronic venous disease (CEAP C2—C5) without compression, (a) with one and (b) two PECS on top of each other, and (c) with one additional conventional stocking covering only the gaiter area to achieve a graduated high pressure profile. Interface pressure was measured in the gaiter area and on the calf.

Results: A significant improvement of EF compared with baseline was found with all three compression modalities. The two superimposed PECS, providing median pressures of 33 mmHg in the gaiter area and 46 mmHg at calf level, increased EF significantly up into the normal range. Increasing the gaiter pressure to 56 mmHg without changing the calf pressure did not result in further improvement.

Conclusions: Two PECS applied on top of each other lead to a maximal improvement of the venous pump function, which cannot be further improved by increasing the pressure in the gaiter area thereby restoring a graduated pressure profile.

INTRODUCTION
External compression of the leg increases venous calf pump function, which can be quantified by measuring the expelled blood volume and ejection fraction (EF) using different plethysmographic methods.1–4 Compared with graduated elastic compression stockings (GECS) exerting a pressure profile higher at the ankle and gradually lower toward the calf, progressive elastic compression stockings (PECS) exerting a higher pressure on the calf than on the ankle, led to a greater increase in the EF in patients with venous disease but did not restore it to the normal range.5

In these experiments PECS were prototypes corresponding to the category of light stockings (about 18 mmHg in the gaiter area). The aim of the study was to determine whether increasing the pressure over the calf could achieve a greater calf pump efficiency in patients with severe superficial venous disease, and if this could be further improved by increasing the pressure over the gaiter area while maintaining the same strong pressure on the calf thereby applying a graduated pressure profile.
MATERIAL AND METHODS

Twenty patients with chronic venous disease (12 female, 8 male, average age 53.7 ± 12.1; range 37—70), presenting with an isolated incompetent great saphenous vein (GSV) and normal deep venous system (rev 3/2), all candidates for varicose vein surgery, were enrolled into this study. Clinical CEAP classes were: C2: five patients, C3: nine patients, C4a: two patients, C4b: two patients, C5: two patients.

Inclusion criteria

Patients had clinical CEAP between C2 and C5; GSV reflux with incompetent terminal and pre-terminal valves, diameter at the level of the junction greater than 10 mm shown by Duplex and reflux longer than 1 s; and good joint mobility enabling patients to perform the exercises requested by the protocol.

Patients who did not fulfill the inclusion criteria and patients who were unable to perform the exercise test described below were excluded.

Patients were informed about the details of the examination and gave their written consent.

With the patient in the standing position, Duplex ultrasound investigation of the superficial and deep veins of the lower extremity was performed in longitudinal view for detecting venous reflux after manual calf compression and during the Valsalva maneuver. A reflux time of more than 1 s was considered to be pathological. A cross-sectional view was used to measure the diameter of the GSV at the sapheno-femoral junction and 5 cm below.

Compression devices

A ready-made, knee length, elastic stocking, with a pressure of 18 ± 2 mm Hg on the ankle and 27 ± 3 mm Hg on the calf was used (Progressiv N'System, Pierre Fabre, Castres, France). The reported pressure ranges corresponded to the values given by the producers for the respective individual leg sizes. The stocking was applied as a single layer and in a double layer version by putting two stockings over each other in order to increase the pressure and maintain an anti-graduated, “progressive” pressure profile. Finally, a third graduated stocking was applied up to the gastrocnemius muscle and then rolled down over the gaiter area to increase the pressure only in this area and restore a graduated pressure profile maintaining the same pressure as before over the calf area.

Interface pressure measurement

The pressure of each compression modality was continuously measured using a newly developed and validated device (Picopress, Microlabitalia, Padua, Italy. The pressure transducer consisted of a flat plastic pressure probe (diameter 5 cm) filled with 2 mL of air for the pressure measurement. Fluctuations of pressure on this probe were transformed into electronic signals (Statham-element) that could be recorded continuously. Two probes were used to measure pressure simultaneously: one at the distal leg, about 12 cm proximal to the medial malleolus (B1 point, which is defined by the transition of the muscular part of the medial gastrocnemius into the tendinous part) and one proximally at the point of maximum calf circumference (C point). Sub-stocking pressure was measured continuously in the supine and the standing position and during the exercise programme.

Measurement of ejection fraction of the venous calf pump

Using strain-gauge plethysmography (AngioFlow2, Microlabitalia, Padua, Italy), EF was assessed following the method described by Poelkens et al. An indium-gallium alloy gauge (diameter of 1 mm) is placed around the leg in the supine position 5 cm distally from the patella and immediately proximal to the upper border of the elastic stocking. The investigation started, after calibration of the device, by elevating the examined leg in order to empty the veins and to record the minimal volume of the leg segment. After 1 min the patient stood up and the volume increase of the calf segment encircled by the strain gauge probe, reflecting venous filling, was measured continuously. “Venous volume (VV)” is defined as the difference between empty and filled veins. During a standardized exercise (walking on the spot with 20 steps in 20 s), the amount of blood expelled towards the heart (EV = expelled volume) reflects the quality of the venous pump. EF was calculated according to the formula 100 × EV/VV. This method was able to assess the hemodynamic efficacy of several compression products in a non-invasive way.

The experiments were carried out under baseline conditions without compression and repeated with the compression stockings applied in one, two, and three layers in a randomized sequence in all patients.

All tests on every patient were done on the same day with an interval of 15 min between each measurement. The measurements were performed 5 min after stocking application with the patient resting in the supine position in a quiet room with constant humidity and temperature.

Discomfort

Discomfort caused by compression devices was assessed using a Visual-Analogue Scale (VAS), where 0 was minimal and 10 maximal discomfort.

Statistics

Based on previous results comparing EF with and without a compression stocking, a sample size of 20 in each group was predicted to have a 95% power to detect a difference between means of 7.91 with a significance level (alpha) of 0.05 (two-tailed) (Rev 3/3). Data were expressed as median values and interquartile ranges.

Non-parametric Friedman tests with Dunn’s multiple comparisons were used to compare the repeated measurements of EF under different compression systems.
Differences with \( p < .05 \) were considered statistically significant.

The graphs and the statistical evaluations were generated using Graph Pad Prism 5 software (Graph Pad, San Diego, CA, USA).

RESULTS

Ejection fraction

Without compression EF was 34.9%, which is significantly lower than the normal values from healthy volunteers (65%) \(^{11}\) (Fig. 1).

EF increased significantly to 53.3% with one PECS \((p < .001)\) and to 67.5 with two PECS superimposed \((p < .001)\). When the third stocking was applied over the gaiter area to restore a graduated pressure profile, EF increased to 64.9%. This difference is statistically significant compared with the baseline values and with the single stocking \((p < .001)\), but not with two stockings exerting a progressive pressure profile.

Pressure measurements

The pressure profile was “progressive” in the first two sets of tests and “graduated” in the third (Fig. 2).

Ease of donning and subjective feelings

The stockings were applied by an experienced person and not by the patients themselves. Donning of the two progressive stockings was easy, but the superposition of the third graduated compression stocking was difficult and even painful for the patient.

With the three stockings applied over each other most patients complained about discomfort and pain (VAS 6; IQR 5–7). In contrast, the two progressive stockings on top of each other were well tolerated and only one patient reported some discomfort (VAS score in this case was 5).

DISCUSSION

The present data clearly show that increasing the pressures to 33 mmHg in the gaiter area and 48 mmHg at calf level by donning two superimposed PECS is significantly more effective in improving venous pumping function versus one PECS providing about half of these pressures. Two PECS were found on average to normalize the EF.

A further increase of the pressure at the gaiter area without changing the calf pressure, to achieve a graduated pressure profile, did not lead to a further improvement of the pumping function but was very uncomfortable or even painful for the patients.

This confirms that high compression pressure in the gaiter area does not contribute to the global venous pumping function and that a graduated pressure profile is not mandatory in the ambulatory patient.

Using the same method to quantify the EF of the calf pump under a standardized walking test, \(^{3}\) it was possible to demonstrate a hemodynamic improvement by applying compression in patients with venous disease in several studies. It could be shown that stiff, non-elastic material, applied with comparable starting pressure, was more powerful than elastic textiles; \(^{11}\) that higher pressures were more effective than lower pressures including elastic stockings; \(^{12}\) and that inelastic bandages maintain their hemodynamic efficiency over time in spite of considerable pressure loss. \(^{13}\) Compared with GECS, PECS were shown to be more effective in improving the venous pumping function with the additional advantage of easier donning and doffing by the patients. \(^{5}\) The same result, a greater hemodynamic effectiveness in increasing EF, occurred with inelastic bandages when applied with higher pressures over the calf than over the gaiter region. \(^{14}\)

The superior hemodynamic effect of progressive compression can mainly be explained by two factors: (a) much more blood is pooled in the calf compared with other regions of the leg; and (b) the calf muscle pump is the most powerful mechanism expelling venous blood from the lower leg. Graduated elastic stockings exerting a pressure of 15–18 mmHg at calf level are able to squeeze the deep veins favoring their emptying. \(^{15}\) It is conceivable that progressive compression devices exerting a pressure of 50 mmHg at calf level are able to compress the deep veins and also the superficial veins even more completely. With these stockings the higher pressure is exerted where it is needed and the intermittent squeezing of the calf during walking will result in a higher degree of expelled volume. \(^{5}\)

The few published data on the superiority of PECS in comparison with conventional GECS refer to a prototype stocking with a rather low pressure of about 18 mmHg in the gaiter area and 27 mmHg over the calf. \(^{5,16,17}\)

This paper sought to answer the question of whether higher pressure over the calf could provide a greater improvement in EF and if this could be further affected by the pressure profile.

A limitation of the study is that this experience is restricted to the short phase of an acute experiment. There are no data on the effects or on the tolerability of the tested compression devices over time. Issues of comfort and compliance deserve a special study. At least in these

Figure 1. Ejection fraction from 20 patients before compression, with one, two PECS, and with one additional GECS.
acute experiments, no major discomfort was reported in patients wearing two PECS. Based on the amazing improvement in EF, which comes close to the efficacy of strong compression bandages, the recommendation to use two low-pressure PECS on top of each other could at least be reasonable in more advanced clinical conditions as long as the patient is active and walking. While resting, one PECS could be removed if two stockings would not be well tolerated. Compared with two superimposed GECS, this regime would also have the advantage of easier applicability concerning donning and doffing.

Another practical consequence, together with the results from our previous work on progressive material, is that the pressure ranges should also be measured at position C and not just in the ankle region.

However, this needs to be investigated in further studies and may be considered in future standardization of compression stockings (Rev. 1/4).

For the time being, the benefit of progressive stockings on EF and venous pumping function in patients with superficial venous incompetence cannot be extended to other clinical conditions such as edema, superficial or deep vein thrombosis, distal leg ulcers, and post-thrombotic syndrome.

The theoretical danger that the inverse pressure gradient could lead to more swelling of the less compressed parts of the distal leg could be refuted at least for single low pressure PECS by a study performed in mobile patients. However, more investigations will be needed to clarify this problem also for higher pressures and in patients with restricted mobility.

**Conclusions**

Double “progressive” elastic stockings achieving pressures of 48 mmHg over the calf and 33 mmHg over the gaiter area lead to a significant improvement and even to a normalization of the EF of the venous calf pump, which is reduced in patients with severe venous disease. Discomfort does not seem to be a major issue. Increasing the pressure over the gaiter area to restore a graduated pressure profile does not achieve a further improvement in venous pump function but causes intolerable discomfort.

**CONFLICT OF INTEREST**

None.

**FUNDING**

None.

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