European Journal of Vascular and Endovascular Surgery 44 (2012) 332–336

Contents lists available at SciVerse ScienceDirect

European Journal of Vascular and Endovascular Surgery

journal homepage: www.ejves.com

High Compression Pressure over the Calf is More Effective than Graduated Compression in Enhancing Venous Pump Function

G. Mosti [a,*], H. Partsch [b]

[a] Clinica MD Barbantini, Via del Calcio n.2, 55100 Lucca, Italy
[b] Medical University of Vienna, Baumeistergasse 85, A 1160 Vienna, Austria

WHAT THIS PAPER ADDS

- This study emphasises the importance of high compression pressure over the calf to enhance venous pumping function in patients with severe venous insufficiency, independently from the pressure profile. In our study, this high pressure was applied by wrapping inelastic material with a 'negative gradient': the compression pressure was stronger over the calf compared to the ankle. This concept is in disagreement with the usual belief that compression should always have a reducing graduated pressure profile from ankle to calf. In the future clinical practice, this means that we do not need to follow dogmatic rules to distribute the pressure of the bandage along the leg but should be guided by the wish to obtain optimal efficacy.

ARTICLE INFO

Article history:
Received 29 February 2012
Accepted 7 June 2012
Available online 21 July 2012

Keywords:
Graduated compression
Negative graduated compression
Ejection fraction
Venous pumping function
Superficial venous insufficiency

ABSTRACT

Background: Graduated compression is routinely employed as standard therapy for chronic venous insufficiency.
Aim: The study aims to compare the haemodynamic efficiency of a multi-component graduated compression bandage (GCB) versus a negative graduated compression bandage (NGCB) applied with higher pressure over the calf.
Methods: In 20 patients, all affected by greater saphenous vein (GSV) incompetence and candidates for surgery (Clinical, etiologic, anatomic and pathophysiologic data, CEAP C2-C5), the ejection fraction of the venous calf pump was measured using a plethysmographic method during a standardised walking test without compression, with GCB and NGCB, all composed of the same short-stretch material. Sub-bandage pressures were measured simultaneously over the distal leg and over the calf.
Results: NGCBs with median pressures higher at the calf (62 mmHg) than at the distal leg (50 mmHg) achieved a significantly higher increase of ejection fraction (median +157%) compared with GCB, (+115%) with a distal pressure of 54 mmHg and a calf pressure of 28 mmHg ($P < 0.001$).
Conclusions: Patients with severe venous incompetence have a greater haemodynamic benefit from NGCB, especially during standing and walking, than from GCB.

Graduated compression providing a decreasing pressure from distal to proximal is the general principle for every kind of compression therapy used today and represents the standard care both in thromboprophylaxis and management of venous and lymphatic disorders. For elastic compression stockings, a continuous pressure reduction from distal to proximal (degressive pressure profile) is postulated as an important quality criterion in regulatory and manufacturing standards.[1–3]

Recent publications have questioned this regulation by demonstrating that elastic stockings with a higher pressure at calf compared to the ankle level were more effective than standard stockings in improving both subjective symptoms and venous pumping function.[4–6]

The aim of our work was to assess if also inelastic bandages exerting a higher pressure over the calf were more effective than

* G. Mosti, Clinica MD Barbantini, Via del Calcio n.2, 55100 Lucca, Italy. Tel.: +39 347 1810280; fax: +39 0583 490050.
E-mail address: jmosti@tin.it (G. Mosti).

1078-5884/$ – see front matter
http://dx.doi.org/10.1016/j.ejvs.2012.06.001

traditionally applied inelastic gradient bandages in improving venous pumping function in patients with advanced venous insufficiency.

Material and Methods

Patients

A total of 20 patients (9 males, 11 females, age average 51.2 years, range 42–68 years) presenting with severe axial reflux in the great saphenous vein (GSV), all candidates for varicose vein surgery, were enrolled into this study.

Inclusion criteria

CEAP (Clinical, etiologic, anatomic and pathophysiologic data) between C2 and C5 (C2 four patients, C3 nine patients, C4 four patients and C5 three patients);

- Significant GSV insufficiency with incompetent terminal and pre-terminal valves, diameter at the level of the junction > 10 mm and reflux > 1 s demonstrated by duplex ultrasound; and
- Ability to perform the exercises requested by the protocol.

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

Venous insufficiency was assessed by duplex-ultrasound investigation of the superficial and deep veins of the lower extremity, performed in longitudinal view for detecting venous reflux during Valsalva's manoeuvre with the patient in the standing position. A cross-sectional view was used to measure the diameter of the GSV in the groin and 5 cm distal.

Patients were informed about the details of the examination and gave their written consent to participate in the study.

The Italian authorities do not require ethical committee approval for observational studies. Furthermore, all procedures were non-invasive, of short duration, performed under the surveillance of doctors and with CE-marked materials and devices that have been used in clinical practice for many years.

Bandages

Measurements were done in baseline condition without compression and repeated after applying multicomponent, multilayer, inelastic bandages exerting two different pressure profiles on the same leg of the patient in a randomised order.

The bandages were wrapped on the lower leg from the base of the toe to the popliteal fossa applying Rosidal K® on top of a padding layer made up with Cellona® synthetic cotton and Mollelast Haft® (Lohmann & Rauscher, Rengsdorf, Germany) to exert two different pressure profiles.

The 'standard' application provided more densely overlapping layers applied with more stretch in the ankle area than over the calf to provide higher distal pressures and a decreasing pressure towards the calf (graduated compression bandages, GCBs). This kind of bandage application was compared with a technique that achieved higher proximal pressures by increasing the amount of strongly applied layers over the calf versus the distal leg, thereby producing a negative pressure gradient (negative graduated compression bandages, NGCBs).

Measuring procedures

Sub-bandage pressures were measured simultaneously on the distal and the proximal lower leg to characterise the pressures of these bandages. A pneumatic technology-based instrument (Picopress®, Microlabitalia, Padua, Italy), validated for precision, linearity and reproducibility,[12] were used. Two transducers (consisting of a flat plastic pressure probe (diameter 5 cm) filled with 2 ml of air) were used to measure the pressure simultaneously at the distal leg, where the muscular part of the medial gastrocnemius turns into its tendinous part (B1 point), and at the maximal calf circumference over the medial gastrocnemius muscle (C point). Sub-bandage pressure was measured in the supine, the standing position and during the exercise programme, simultaneously with the continuous registration of the plethysmographic changes described below.

Primary outcome was the quality of the venous calf pump quantified by measuring its ejection fraction (EF) during a standardised walking exercise, without and with bandages applied by the two different techniques.

EF was assessed using strain-gauge plethysmography (Angioflow2, Microlabitalia, Padua, Italy) following the method described by Poelkens et al.[7] An indium–gallium alloy gauge (a diameter of 1 mm) is placed around the leg in the supine position 5 cm distally from the patella and proximally to the compression bandage. The investigation starts, after calibration of the device, by elevating the examined leg to empty the veins and to record the minimal volume of the leg segment. Then, the patient stands up and the volume increase of the calf segment encircled by the strain-gauge probe, reflecting venous filling, is measured continuously. Venous volume (VV) is defined as the difference between empty and filled veins. During a standardised exercise (walking on spot with 20 steps in 20 s), the amount of blood that is expelled towards the heart (EV = expelled volume) reflects the quality of the venous pump. EF (%) is calculated according to the formula: $100 \times EV/VV$.

This method has previously been demonstrated to be able to assess the haemodynamic efficacy of compression devices in a completely non-invasive way.[8–11]

Each patient was investigated on the same day with an interval of 15 min between each measurement, with the patient resting in the supine position in a quiet room with constant humidity and temperature.

Statistics

In the present work, median values and interquartile ranges (IQRs) are given.

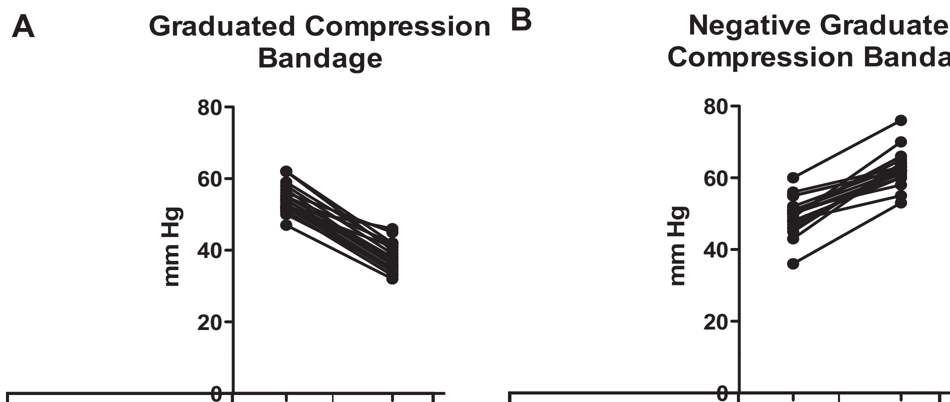
The *t*-test and one-way analysis of variance (ANOVA) with Tukey's multiple comparisons were used to compare the repeated measurements under different compression systems with the baseline. The Pearson test was taken for quantifying correlations. Differences with a $P < 0.05$ were considered statistically significant.

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

Results

Under the GCBs, supine interface pressure decreased from 53.5 mmHg (IQR 52–56.75) at B1 to 37.5 mmHg (IQR 35–41) at C (Fig. 1(A)). With NGCBs, pressure increased from 50 mmHg (IQR 47.25–54.25) at B1 to 62 mmHg (IQR 60.25–64.00) at C (Fig. 1(B)).

For both types of bandages, standing pressure was significantly higher than supine pressure, both at position B1 and at C ($P < 0.001$ *t*-test) (Fig. 2). While at position B1 there was no significant



(A)	B1	C
Minimum	47.00	32.00
25% Percentile	52.00	35.00
Median	53.50	37.50
75% Percentile	56.75	41.00
Maximum	62.00	46.00

(B)	B1	C
Minimum	36.00	53.00
25% Percentile	47.25	60.25
Median	50.00	62.00
75% Percentile	54.25	64.00
Maximum	60.00	76.00

Figure 1. Sub-bandage pressure profile with Graduated Compression Bandages (A) and Negative Graduated Compression Bandages (B).

difference between the two bandage types in the supine and in the standing positions, the negative graduated bandage produced significantly higher pressure over the calf in supine (62 mmHg (IQR 60.25–64) vs. 37.5 mmHg (IQR 35–41)) and standing positions (75.5 mmHg (IQR 69.25–82) vs. 59 mmHg (IQR 52.5–66.5) ($P < 0.001$)).

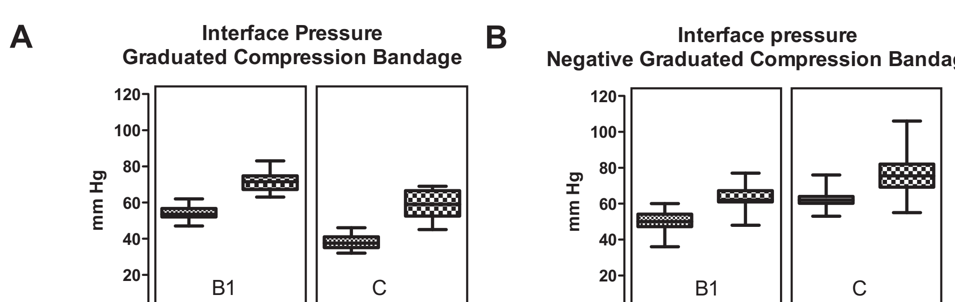
The maximal pressure peaks, corresponding to muscle systole during walking exercise, were significantly higher over the C area with NGCB (93 mmHg, IQR 91.25–106.3) than with GCB (67 mmHg (IQR 63.5–69) ($P < 0.001$) while there was no significant difference between the corresponding values for the B1 area (Fig. 3).

EF without compression was 32.9% (IQR 24.8–41.6), which was significantly lower than our normal values from healthy volunteers (65%, IQR 53.7–67,8).[8] This shows that all enrolled patients had a severely diminished venous pumping function.

EF increased significantly to 75.6% (IQR 64.2–79.4) with GCB ($P < 0.001$) and to 89.1% (IQR 85. 96) with NGCB ($P < 0.001$) (Fig. 4). Compared with GCB, the additional improvement achieved by NGCB was significant (repeated ANOVA and Tukey's multiple comparisons, $P \leq 0.001$). There was a significant correlation between the peak pressure over the calf and the EF (Fig. 5).

Discussion

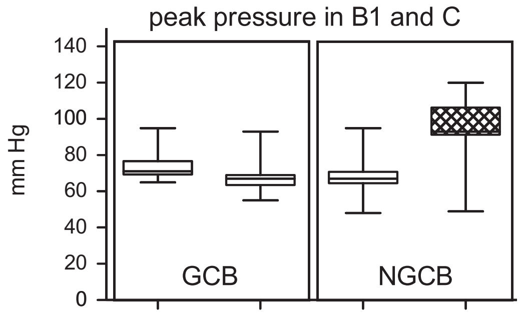
Several investigations using the same methodology as in this trial were able to specify some properties of compression devices for maximising the venous pumping function in patients with venous insufficiency in comparison to that of normal control subjects.[8] It could be demonstrated that, with the same pressure, inelastic material is more effective than elastic and that higher sub-bandage pressure is more effective than low pressure.[8–10] It was also shown that inelastic bandages maintain their effectiveness over time despite of a significant pressure loss.[11] This is very important in clinical practice as inelastic bandages lose pressure very quickly following application. Finally, inelastic bandages up to a pressure of 40 mmHg were shown to be able to improve venous



(A)	B1 supine	B1 standing	C supine	C standing
Minimum	47.00	63.00	32.00	45.00
25% Percentile	52.00	67.25	35.00	52.50
Median	53.50	71.50	37.50	59.00
75% Percentile	56.75	74.75	41.00	66.50
Maximum	62.00	83.00	46.00	69.00

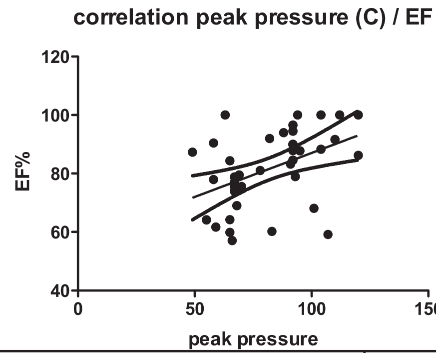
(B)	B1 supine	B1 standing	C supine	C standing
Minimum	36.00	48.00	53.00	55.00
25% Percentile	47.25	61.00	60.25	69.25
Median	50.00	62.00	62.00	75.50
75% Percentile	54.25	67.25	64.00	82.00
Maximum	60.00	77.00	76.00	106.0

Figure 2. Sub-bandage pressure in supine and standing position above the inner ankle (B1) and at calf area (C) with Graduated Compression Bandages (A) and Negative Graduated Compression Bandages (B). Both bandages show significantly higher pressure in standing compared to supine ($P < 0.001$), NGCB shows significantly higher pressure over the calf in supine and standing position compared to GCB ($p < 0.001$).



	B1	C	B1	C
Minimum	65.00	55.00	48.00	49.00
25% Percentile	69.25	63.50	64.50	91.25
Median	71.00	67.00	67.00	93.00
75% Percentile	76.75	69.00	70.75	106.3
Maximum	95.00	93.00	95.00	120.0

Figure 3. Peak pressure during exercise at ankle (B1) and calf area (C) with Graduated and Negative Graduated Compression Bandages. In contrast to GCB the peak pressures achieved by NGCB are significantly higher over the calf than over the ankle area ($p < 0.001$).



Number of XY Pairs	40
Pearson r	0.4462
95% confidence interval	0.1563 to 0.6653
P value (two-tailed)	0.0039
P value summary	**
Is the correlation significant? (alpha=0.05)	Yes
R square	0.1991

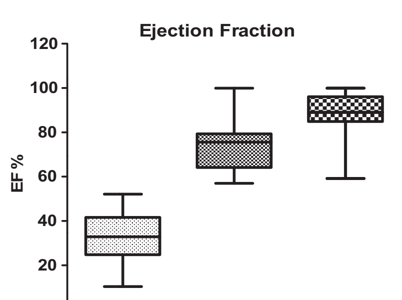
Figure 5. Ejection fraction is positively correlated with peak pressure over the calf (Pearson $r = 0{,}45$, $p < 0{,}01$).

pumping function in patients with mixed arterial-venous ulcers, without impeding the arterial flow.[12]

The question how the pressure should be distributed along the leg to produce an optimal support of the venous pump has not been investigated up to now.

In landmark publications[13] and in papers advocating adequate training courses for nurses,[14] a gradual fall of compression pressure from distal to proximal is considered to be an important feature for all kinds of compression treatment. This is also frequently postulated in advertisement material of bandage products under the term ‘gradient compression’, but up till now no data on the importance of this concept for stimulating the calf muscle pump were available.

In a recent study, we could demonstrate that ‘negative-gradient’ compression stockings with higher pressures over the calf resulted in a greater increase of the EF of the calf-muscle pump.[6] This stimulated us to question the dogma that a pressure gradient is a prerequisite for any kind of good compression therapy, including inelastic compression bandages.



	baseline	GCB	NGCB
Minimum	10.45	57.07	59.20
25% Percentile	24.80	64.18	84.96
Median	32.89	75.59	89.10
75% Percentile	41.64	79.38	96.06
Maximum	52.12	100.0	100.0

Figure 4. Ejection fraction (%) in baseline conditions, with GCB and NGCB. (Differences between baseline and both bandages, but also between the two bandages are significant ($p < 0.001$).

In fact, two main mechanisms of action could theoretically be in favour of a superior effect of stronger compression over the calf:

1. A more intense squeezing effect on the venous blood pooled in the calf (and not in the ankle), with every step during walking, due to the higher external pressure over the pumping chamber. Compared to GCB, this higher pressure over the calf muscle pump is exerted by NGCB not only in the supine and in the standing positions but especially during exercise when pressure peaks in a range between 50 and 120 mmHg (median 93 mmHg) could be registered. This massaging effect is certainly more efficient over the calf where a significant amount of blood is pooled than over the distal leg (Fig. 5). The high compression peaks do not interfere with the intra-arterial pressure, which is augmented by the hydrostatic pressure during standing and walking.
2. A more complete hindrance to venous reflux during walking. As we know from other studies, external pressures in the range of 80 mmHg are required in the upright position to achieve a maximal narrowing both of superficial and deep veins.[15] Short intermittent phases of venous occlusion during walking lead to an intermittent reduction of venous reflux and reduce ambulatory venous hypertension.[16] Such an effect could be demonstrated even in patients without venous valves (avalvulia) and has been called an ‘artificial valve mechanism’.[17] Less pressure is less effective.[16]

Actually, the present study revealed a significant haemodynamic superiority of NGCB in comparison to GCB in patients with severe venous incompetence characterised by long axial reflux (>1 s) in significantly dilated saphenous veins (>10 mm diameter), all with a pathologically reduced EF.

In all our previous studies showing a positive correlation between compression pressure and EF, pressure measurements were performed at B1. From the present study, it becomes clear that the pressure of the compression device measured directly over the pumping chamber has more relevance than a pressure gradient.

Finally, it is worthwhile to underline that pressure peaks between 60 and 80 mmHg can only be achieved and tolerated if non-yielding, stiff material is used. This was shown in a previous trial in which also elastic bandages applied with a resting pressure of 60 mmHg had been tested, which were barely tolerated for the short time of the experiments.[8]

What are the consequences and the limitations of this investigation?

Our study showed that the pressure distribution of a bandage does not need to follow dogmatic rules but should be guided by the wish to obtain optimal efficacy.

Despite the fact that inelastic GCBs are able to normalise the pumping function in patients with venous insufficiency, the present study has demonstrated that a higher pressure over the calf realising a negative graduated pressure profile is able to maximally increase the venous pumping function during walking.

It could well be that a GCB producing the same high pressures over the calf, as achieved in this study by bandages with a negative gradient or a bandage exerting about the same high pressure along the leg, could have produced an equally positive augmentation of the calf pump. However, a traditional gradient profile providing calf compression in the range of 50–60 mmHg would require a pressure in the ankle region of 80–90 mmHg, which could be not well tolerated and cause side effects, especially over the bony prominences and the tendons in that region.

Our study was concentrating on changes of the venous pumping function immediately after bandage application. Neither the subjective tolerance of the bandage by the patient nor any clinical outcomes including side effects were taken into account. Future studies will be needed to assess the long-term tolerance of such anti-gradient bandages, to evaluate their potential role to promote venous ulcer healing, and to rule out negative effects especially concerning distal oedema. As a practical consequence, we consider a high working pressure over the calf to be more important than a pressure gradient and recommend applying inelastic bandages in mobile patients with severe venous insufficiency with initial calf pressures in the range of 60–80 mmHg.

Conclusions

Bandages exerting a higher pressure over the calf compared to the ankle were more effective in increasing the venous pumping function in patients with venous insufficiency compared to graduated compression. This effect may be explained by squeezing out more blood from the pumping chamber of the lower leg. The dogmatic rule that compression needs a graduated pressure profile is in disagreement with the presented results at least in the moving patient.

Conflict of Interest/Funding

None.

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