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A New Two Component Compression System Turning an Elastic Bandage into an Inelastic Compression Device: Interface Pressure, Stiffness, and Haemodynamic Effectiveness

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WHAT THIS PAPER ADDS

This study shows, for the first time, how an elastic compression material can exert a consistent pressure independently of the leg shape and the ability of healthcare providers. It also demonstrates how this elastic material can be easily transformed into an inelastic one by adding special patches, thereby significantly improving its haemodynamic effectiveness. These patches applied to the test material could also be used with other elastic material. In addition, this concept could stimulate research into other systems to transform elastic into inelastic material. This adds the advantage of easy application of elastic material and longer consistency of exerted pressure to the superior haemodynamic effectiveness of inelastic compression.

Introduction: Bandage application does not exert consistent compression pressure, leading to extremely variable compression when applied to patients. A new elastic bandage can exert a predefined pressure independently of healthcare providers and the size of the wrapped limb. The bandage system includes a series of non-stretchable patches that when applied to the bandage make it stiff. The aim of this work was to assess, in an experimental setting, the venous ejection fraction (EF) from the lower leg and the tolerability of this new bandage in a group of patients affected by superficial venous incompetence.

Methods: EF was measured using strain gauge plethysmography under baseline conditions and the bandage was applied with a supine pressure of 20 and 30 mmHg, with and without the stiff patches, in 25 patients with severe venous reflux in the great saphenous vein. The interface pressure of the bandages was measured simultaneously in the medial gaiter area.

Results: All patients showed EF values that were significantly reduced compared with normal individuals. Elastic bandages with an average pressure of 20 and 30 mmHg in the supine position achieved a slight improvement in EF, and, after applying non-stretchable patches on the same bandage with similar resting pressure, EF was restored to its normal range ($p < .001$). Improvement in EF correlates with the pressure differences between standing and lying pressure and between muscle systole and diastole during exercise.

Conclusion: This study confirms that inelastic is much more effective than elastic compression for improving impaired venous haemodynamics. The test material can be applied with a predetermined pressure, which considerably enhances the consistency of application, and it is easily transformed into an inelastic system just by applying stiff patches without any stretch and without significantly increasing the comfortable supine pressure.

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INTRODUCTION

Several studies[1–5] have shown that bandage application does not exert consistent compression pressure (CP), leading to extremely variable applied CP. In fact, the medical field of compression treatment is maybe the only one where quantitative dosage has almost never been measured, despite outcomes largely depending on it. As a consequence, CP is generally unknown, leading to doubtful outcomes in published studies on compression therapy.[6]

One recent invention addressing this inconsistency consists of a new medical bandage that gives a predefined pressure independently of the applier and the size of the wrapped limb. In order to ensure this universality feature,

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highly elastic material must be used according to a very low static stiffness index (SSI),[7] which is the difference between standing and supine pressure. Inelastic material (maximal extensibility less than 100%), providing high SSI, is more effective in improving the impaired venous haemodynamics than elastic material with an extensibility of more than 100%.[8] This is due to the stronger compression effects during muscle systole squeezing out the veins and blocking venous reflux.[9] During muscle contraction, for example during walking, elastic material does not provide pressure peaks high enough to improve the venous pumping function.[8,9] In order to add this feature, the bandage system includes a second component that consists of a set of not-stretchable patches of hook material to provide a stiff outer layer.

The aim of this work was to assess the effect of this new two component system on the ejection fraction (EF) depending on two different baseline pressures with and without the additional application of patches in an experimental setting. In addition, data on short-term tolerability of the compression system were collected.

METHODS

In this experimental study, 25 legs from 25 patients (12 males and 13 females, mean age 62 ± 11 years), all affected by clinically significant reflux in the great saphenous vein (GSV), with clinical stage C2—C5 were investigated. Patients suffering from reflux in the GSV and on the waiting list for venous ablation were selected to reduce the variability of haemodynamic baseline characteristics.

Inclusion criteria

The inclusion criteria were as follows:

- Clinically severe venous reflux in the GSV with peak reflux velocity of more than 30 cm/second and a duration of more than 3 s according to Duplex ultrasound, presenting diameter of GSV of more than 10 mm assessed 2 cm below the junction and further down along the saphenous trunk. Reflux was elicited after sudden release of calf compression in the standing position.
- Age between 18 and 80 years.
- The ability to perform the physical exercise requested to assess venous pumping function.

All individuals were informed about the investigation and gave their written informed consent. In Italy, spontaneous studies comparing CE marked products do not require ethics committee approval. The study complied with Ethical Principles of the Helsinki Declaration for Medical Research involving human subjects.

Compression material

A new compression system was tested (Lundatex system, PressCise, Herrljunga, Sweden) comprising an elastic bandage as the first component and inelastic patches (made in a hook material) as the second stiff component. Bandages exerting two different pressure levels were used: 20 mmHg (Lundatex medical 20) and 30 mmHg, (Lundatex medical 30) with and without the stiff patches (PressPatches). The bandage was applied from the base of the toes up to 1 cm below the strain gauge in a spiral fashion according to two sets of marker lines that must be aligned to exert the predefined pressure level (Fig. 1A): one longitudinal marking to make the overlap constant and several markings with constant distance that are perpendicular to this longitudinal marking. These marks must be aligned for each bandage turn. Given the specific elasticity property of the bandage material, these two features—higher tension and less curvature—compensate each other, according to Laplace's law, resulting in a constant sub-bandage pressure along the leg. When wrapped according to the manufacturer's instructions, the bandage should provide a precise resting pressure that can be predefined at 20 mmHg,

Figure 1. The bandage is applied to the leg. The two sets of bandage markings necessary to exert the declared pressure are visible (A). The bandage is covered by overlapping patches on the calf area (B). The final fixation system is applied over the tibial crest (C) and can be lifted, when necessary, for bandage adjustment to new leg sizes (D).

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