

# A Wearable Compression Device to Normalise Calf Muscle Pump Function in Chronic Venous Insufficiency for Each Postural Position

Giovanni Mosti <sup>a,\*</sup>, Hugo Partsch <sup>b</sup>

<sup>a</sup> Clinica MD Barbantini, Via del Calcio n.2; 55100 Lucca, Italy

<sup>b</sup> Professor Emeritus, Department of Dermatology, Vienna Medical University, Vienna, Austria

## WHAT THIS PAPER ADDS

The currently used compression devices exert pressure that is usually inadequate to have effective impact on the veins in different body positions. The newly tested compression device is easy to apply and able to automatically adjust its pressure to the venous pressure in any body position, thereby counteracting venous pressure better than elastic stockings in the standing and walking positions. The device was comfortable in all tested body positions. These characteristics could influence future clinical practice by increasing patient compliance with compression.

**Background:** For the currently used compression therapy, the applied compression pressure is usually inadequate to exert an effective impact on the veins in different body positions. The aim was to assess the venous ejection fraction achieved by a new compression device which automatically adjusts the interface pressure to body position in an acute experimental setting.

**Methods:** A new portable, battery driven compression device providing pressure adjusted to allow for body position, and connected to a less or very stiff calf cuff wrap was tested. In patients with superficial venous incompetence, the ejection fraction (EF) of the calf pump was measured by strain gauge plethysmography. Applied in a random sequence, values achieved without compression, with the two cuffs, and with compression stockings exerting 23–32 mmHg, were compared. The applied compression pressures were simultaneously recorded in the supine and standing positions, and during walking. Comfort was assessed by a visual analogue scale (VAS) with 0 corresponding to very low comfort and 10 to very comfortable.

**Results:** In 16 patients with CEAP clinical stage C3–C6, EF without compression was 37%, increasing to 46.9% with stockings, to 64.8% ( $p < .001$ ) by less stiff and to 75.5% ( $p < .001$ ) by stiffer wraps. The median interface pressure (supine/standing) was 31/56 mmHg for the less stiff device, 32/68 mmHg for the stiffer device, and 23/26 mmHg for the stockings. The static stiffness index and the walking pressure amplitudes were significantly higher than those generated by the stocking, and the highest values were found with the stiffer wrap material. The device comfort was high both in the supine and standing positions (VAS  $8 \pm 2$ ).

**Conclusions:** The tested devices were comfortable at rest and haemodynamically effective during walking by automatically adjusting compression pressures to body position. They are significantly more effective than elastic stockings in improving EF. The system is able to overcome the problems of fast pressure loss by continuously re-adjusting the compression pressure.

**Keywords:** Compression therapy, Inelastic wraps, Miniature air pump, Interface pressure, Venous ejection fraction

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## INTRODUCTION

The fact that the pressure of a compression device is critical to its efficiency has gained increasing interest in recent years. Several experimental trials have established dose response relationships between exerted pressure and

oedema reduction<sup>1–3</sup> and have investigated the influence of compression pressure on venous ejection from the lower leg in patients with venous insufficiency.<sup>4–6</sup> It became clear that the compression pressure varies considerably in different body positions depending on the elastic properties of the material used but “optimal” pressure settings are still a matter for debate. Compression pressure, even when wrapping with the same material, may be extremely variable depending on the skill and experience of the bandager. In addition, the compression pressure will reduce after application, especially with stiffer, short stretch materials

\* Corresponding author. Clinica MD Barbantini, Via del Calcio n.2, 55100 Lucca, Italy.

E-mail address: [giovanni.mosti10@gmail.com](mailto:giovanni.mosti10@gmail.com) (Giovanni Mosti).

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because of the reduction in tissue volume caused by oedema reduction and to some extent, by compression material fatigue.<sup>7</sup>

A new device (Intelli ~ Press™, ACI Medical, San Marcos, CA, USA) has been developed recently to counteract venous pressure in any body position, by applying predictable and consistent compression pressures that automatically adjust to body position.

The aim of this study was to compare the efficacy of this new device, connected to a more or less stiff wrap, with that of conventional elastic compression stockings regarding the pressures achieved and an improvement of the calf pump function in patients with chronic venous insufficiency. Additional aims were to check whether the device accurately determined body position, to assess the comfort of device, and to identify any safety concern and risk to the patients at least during the short test time.

## METHODS

This was an acute, experimental study performed in 16 patients (10 males, six females aged  $49.8 \pm 12.3$  years; range 31–76 years) with great saphenous vein (GSV) incompetence, all of them candidates for GSV ablation. The clinical signs according to the CEAP classification were C2 in six, C3 in four, C4 in four and C5 in two cases.

The incompetence of the GSV, including terminal and pre-terminal valve incompetence, was assessed using a Duplex scanner (Esaote Technos with linear probe 7.5–10 MHz; Esaote s.p.a. Genoa, Italy) with the patient in the standing position leaning on the non-examined leg. The venous diameter in the standing position two cm below the junction was  $>1$  cm and venous reflux time after manual calf compression was  $>3$  s. None of these patients was affected by deep venous insufficiency or obstruction.

Tests were carried out after the patients gave informed consent, in agreement with the Helsinki declaration.

Each patient was investigated four times consecutively:

1. without compression
2. with a knee length compression stocking (23–32 mmHg)
3. with the less stiff wrap material of the Intelli ~ Press™ device
4. with the stiffer wrap material of the Intelli ~ Press™ device.

The sequence of the measurements was performed in a randomised order.

### Assessment of ejection fraction (EF) of the calf muscle pump

A plethysmographic method which has been described in detail in previous publications was used.<sup>4–7</sup>

A strain gauge probe (Angioflow2®, MicrolabItalia, Padua, Italy) was positioned around the calf proximal to the compression device.<sup>8</sup> Volume changes were registered starting with elevated legs to empty the veins. Then the

patient stands up to fill the veins. After reaching a plateau the venous volume is determined and the patient is asked to walk on the spot, which induces a volume reduction depending on the quality of the venous pump function. The resulting volume decrease (ejection volume) is measured. Ejection fraction (EF) is defined as the ejected volume as a percentage of venous volume. Normal values of EF are  $> 60\%$ , and patients with venous insufficiency have been shown to have much lower values.<sup>4–6</sup>

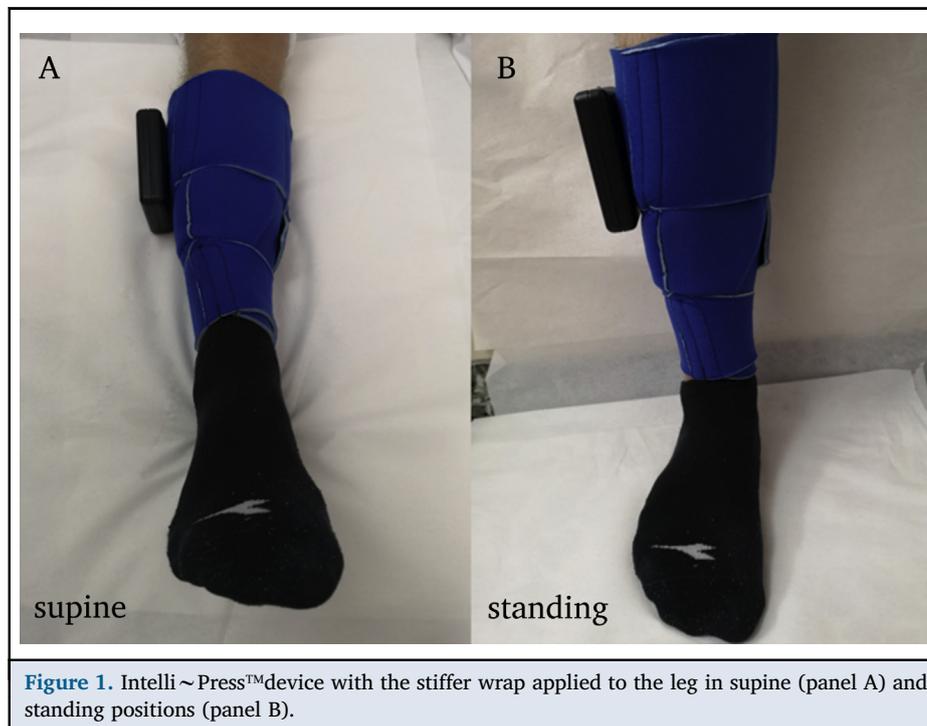
### Compression devices

Knee length elastic compression stockings (Gloria 261®, Gloriamed, Menaggio, Italy) labelled to exert 23–32 mm Hg were used.

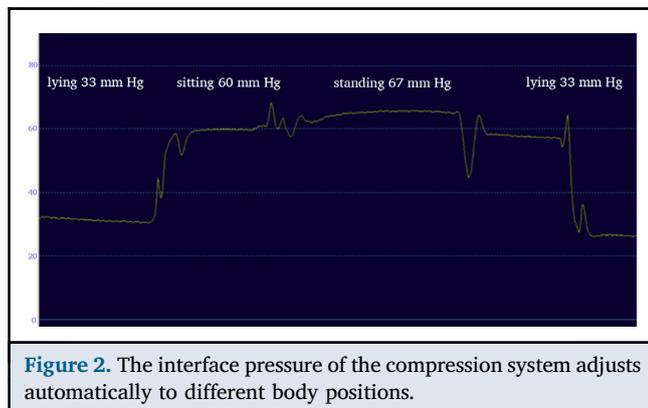
Intelli ~ Press™ is made up of a small, battery powered control module attached to a calf wrap that contains an air bladder. The control module applies programmed pressures to the calf based on body position and reflects the hydrostatic intravenous pressure that is due to the height of the column of venous blood between the heart and the lower leg. This is accomplished by identifying the postural position of the patient with the use of accelerometers. Residing within the control module are the accelerometers, pressure sensing electronics, a miniature air pump, and batteries. The wrap is made up of an unbroken loop (UBL) and laminate hook and the loop can be adjusted. At the present time, for testing reasons, two wraps with more or less stiff fabric were designed. The wrap configuration allows for easy application to the limb (Fig. 1). The device applies a relatively low pressure of approximately 35 mmHg when snugly applied in the supine position and a much higher pressure of 65 mmHg when standing (Fig. 2). During ambulation, the calf muscle pump action produces a large difference between systolic and diastolic pressure because of the nature of the short stretch wrap material. The high pressure oscillations during walking exert a massaging effect on the calf supporting the venous ejection fraction from the leg. When applied for longer, the pump will maintain programmed pressures although swelling and limb volume are reduced. The pre-programmed pressure profile avoids the need for skilled application by a clinician and applying high pressure only when required contributes to patient comfort.

### Measurement of interface pressures

The interface pressures of the applied devices were registered continuously during the plethysmographic investigation by using a flat, air filled pressure probe (PicoPress®, MicrolabItalia, Padua, Italy) attached to the medial side of the lower leg, about 12 cm above the ankle, the so called B1 point, where the tendinous part of the gastrocnemius muscle turns into the muscular part. The static stiffness index (SSI) was calculated by subtracting the standing pressure from the supine pressure. The walking pressure amplitude (WPA) was calculated by subtracting the diastolic values from the systolic pressure peaks during walking exercise.<sup>5</sup>



**Figure 1.** Intelli~Press™ device with the stiffer wrap applied to the leg in supine (panel A) and standing positions (panel B).



**Figure 2.** The interface pressure of the compression system adjusts automatically to different body positions.

### Compression device comfort

Compression device comfort was assessed by means of a visual analogue scale (VAS), with 0 corresponding to very low comfort and 10 to very comfortable.

### Statistics

The order of the examinations for testing the three devices followed a randomisation list (<https://www.random.org/lists/>). The randomisation was concealed from the examiner who was unaware what kind of calf sleeve he was testing.

In a previous study<sup>6</sup> an increase in mean EF values was demonstrated in 15 patients with chronic venous insufficiency from  $30.93 \pm 6.25\%$  to  $47.84 \pm 9.9\%$  with elastic bandages and to  $67.03 \pm 9.73\%$  by applying inelastic bandages. Based on these data<sup>6</sup> a sample size calculation was performed (GraphPad, StatMate2, San

Diego, CA, USA). It was shown that a sample size of 14 in each group had a 95% power to detect a difference of means with a significance level (alpha) of 0.05 (two tailed) for inelastic material at 40 mmHg. Sixteen patients were included in this study to prevent missing data from dropouts.

Medians and interquartile ranges are given. To compare the effects of multiple treatments in the same individuals Friedman statistics were used. Additionally, the difference between the values in all groups was calculated using the Wilcoxon signed rank test. The graphs and the statistical evaluations were generated using Graph Pad Prism, version 6 software (Graph Pad, San Diego, CA, USA).

## RESULTS

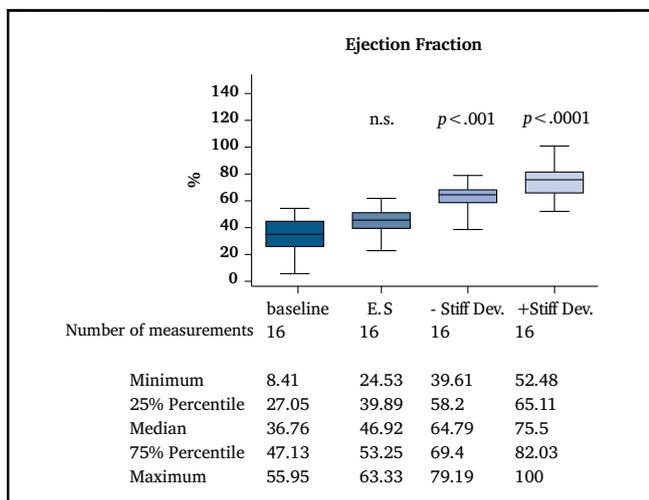
### Ejection fraction

EF increased from the baseline of 36.8% (IQR 27.05–47.13) to 46.92 (IQR 39.89–53.25) with elastic stockings and to 64.8 (IQR 58.2–69.4) and 75.5 (IQR 66.11–82.03) with the less and stiffer wraps respectively.

The EF increase was statistically significant with both wraps ( $p < .0001$ ) in contrast to the stocking. Both wraps were able to restore the ejection fraction from the lower leg to the normal range. The highest increase was achieved with the stiffer wrap (Fig. 3).

### Pressure measurement

Interface pressures were significantly higher under both wraps than under compression stockings ( $p < .0001$ ) (Fig. 4). The supine interface pressure was 23 mmHg



**Figure 3.** Ejection fraction, the ratio between ejected volume and venous volume (normal range >60%) is markedly reduced in patients with venous disease compared with normal values. Comparing with this reduced baseline value, ejection fraction slightly increases with compression stockings (n.s.) but significantly increases and is restored in the normal range with both Intelli~Press™ wraps ( $p < .001$  for the less stiff device) with the stiffer wrap material providing the best result ( $p < .0001$ ). E.S. = elastic stockings; -Stiff Dev. = less stiff device; +Stiff Dev. = stiffer device.

(IQR 21–24.7 mmHg) with stockings, 31 mmHg (IQR 26–34.5 mmHg) with the less stiff wrap, and 35 mmHg (IQR 27.7–39.5 mmHg) with the stiffer wrap. By moving to the standing position, pressure increased to 26 mmHg (IQR 25–28.5 mmHg) with elastic stockings, 56 mmHg (IQR 46.5–59) with less stiff wrap and to 68 mmHg (IQR 60–73.2 mmHg) with the stiffer wrap.

SSI and WPA were significantly higher with both Intelli~Press™ wraps than with elastic stockings ( $p < .0001$ ). The highest value was achieved with the stiffer device (Fig. 5).

**Body position assessment**

In all tests the new device correctly identified the patient position. The micropump applied the pressures for which it was programmed and there were no safety related problems with its use.

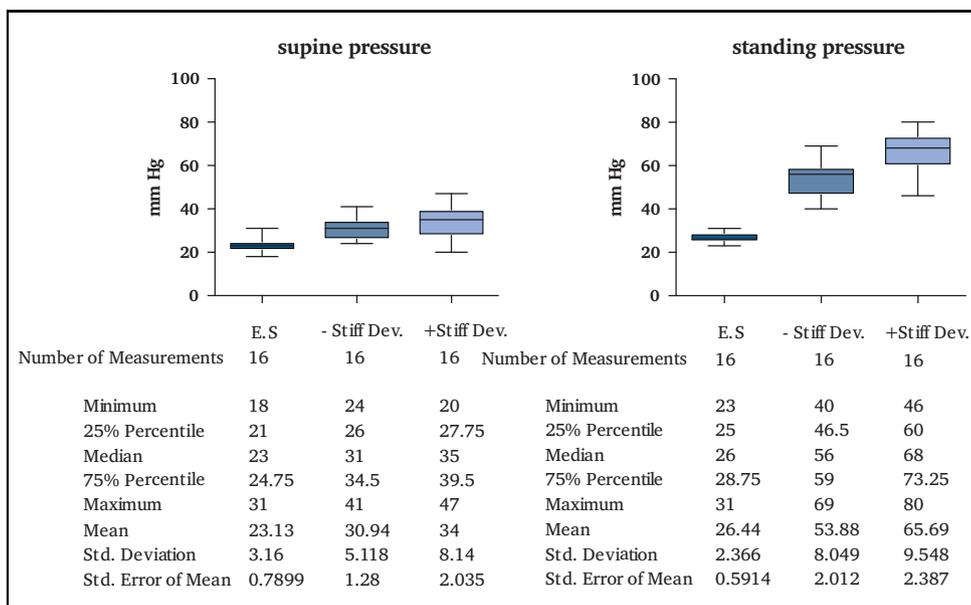
**Compression device comfort**

Elastic compression stockings and the new device (with both calf cuffs) were reported to be very comfortable by all the patients with a VAS value of 8 (IQR 8–9) for all the devices without any difference (n.s.) (Fig. 6).

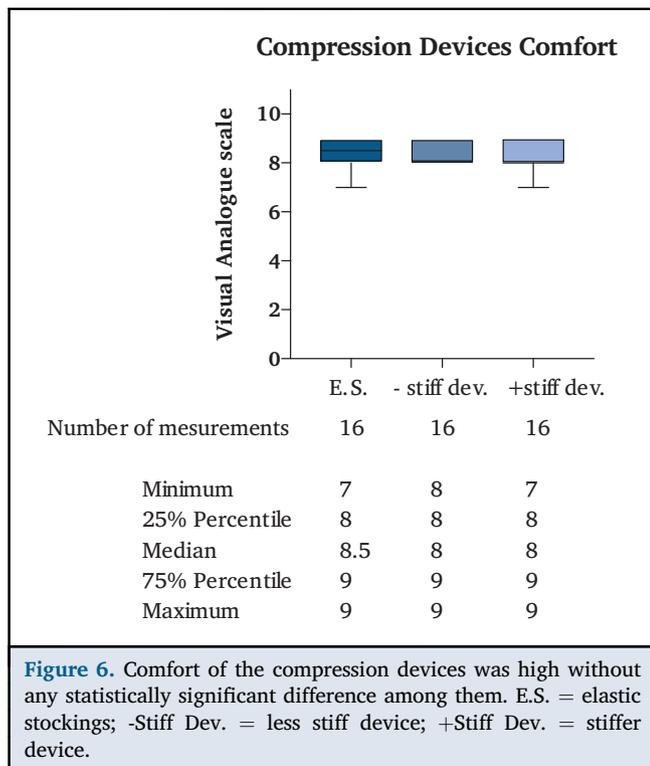
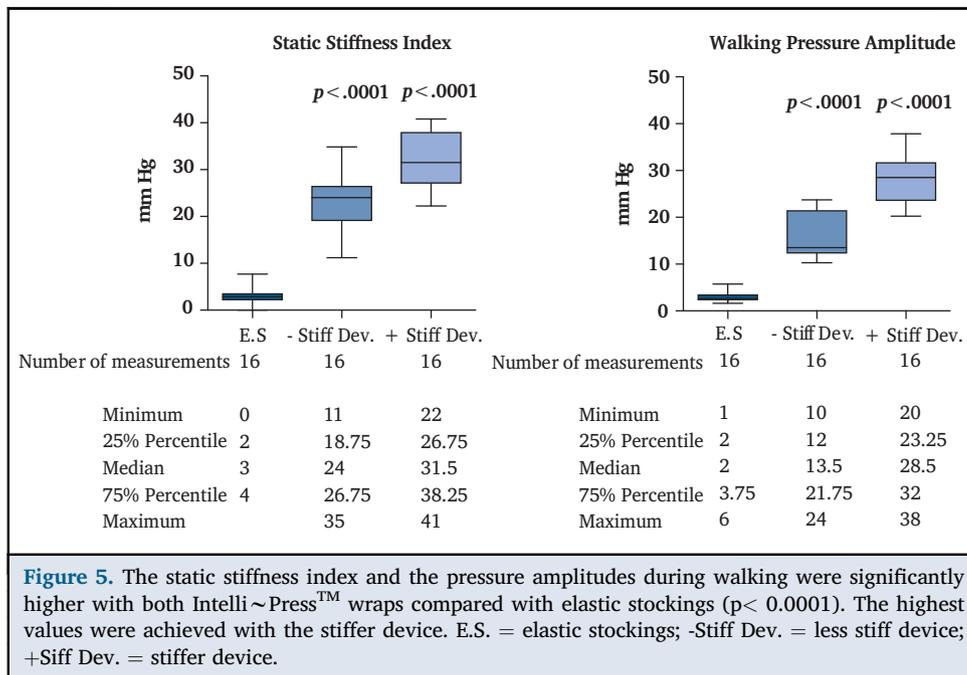
**DISCUSSION**

This study has demonstrated the haemodynamic superiority of a stiff cuff on the leg when the pressure in the standing position goes up to more than 60 mmHg.

The compression pressure corresponds to the dosage of the therapy and decides the clinical effectiveness of compression therapy. Based on several experimental studies it is known that low pressure can already reduce oedema,<sup>2,3,9</sup> but that much higher pressures are required to improve venous haemodynamics. Stiffer, short stretch compression material applied with strong pressure fulfils the requirement to counteract gravity by narrowing the leg veins in the upright position, and at the same time to reveal low, well tolerated resting pressures. This was shown by



**Figure 4.** The interface pressure measured in the supine and standing positions under elastic stockings and the two Intelli~Press™ wraps is higher for both wraps. The highest values were achieved with the stiffer device. E.S. = elastic stockings, -Stiff Dev. = less stiff device, +Stiff Dev. = stiffer device.



duplex and magnetic resonance imaging (MRI) investigations performed in the sitting and standing positions.<sup>10,11</sup>

However, the proper application of short stretch compression is not easy and needs well trained staff, which is rarely the case in regular medical practice.<sup>12,13</sup>

Another disadvantage is that such bandages will lose pressure very quickly so that their effectiveness may decrease slightly.<sup>7</sup>

An intelligent compression system provides adequate pressures after application and adjusts to the need for higher pressures in the upright position and is therefore an important step in the direction of a self-applicable compression therapy, overcoming the problems of inadequate pressures and pressure loss after application.

The tested devices solve these problems as they are able to automatically readjust the pressure depending on body position and as pressure tends to decrease due to leg volume reduction. The model with the stiffer wrap generated higher pressures during standing and walking and showed higher values of static stiffness index and of walking pressure amplitude. The higher pressure during walking and the strongest massaging effect explain the stronger effect in improving the reduced calf pump function.

By contrast, the haemodynamic effects of the elastic stockings are rather poor. They show only a very modest pressure increase during standing and walking, low SSI and WPA and, as a consequence, a very weak improvement of EF.

From duplex and MRI investigations it is known that stockings lead only to a minor narrowing of the lower leg veins in the upright position, which explains their haemodynamic inferiority.<sup>14</sup> By contrast, short stretch bandages applied with strong pressure can occlude the veins during standing and walking, intermittently leading to a kind of artificial valve mechanism, thereby reducing venous reflux, increasing calf pumping function, and, finally, reducing ambulatory venous hypertension.<sup>15,16</sup>

For these reasons the Intelli~Press™ device can be used in all the clinical scenarios requiring a haemodynamic effect including acute deep or superficial venous thrombosis, acute inflammatory stages, post vein procedures, and venous ulcers.

The ease of application, removal, and operation of the compression system supports its acceptance by the intended users.

While this device technology has obvious indications for treating venous and lymphatic problems, there is a significant population with mixed arterial and venous disease in whom existing compression therapy may be inappropriate. Intelli~Press™ can be programmed to address these patients by applying pressures lower than elastic stockings when in the supine position but with higher pressures applied in vertical posture positions when both intravenous and intra-arterial pressures are increased.

A weakness is that it was an acute pilot study not allowing any conclusions regarding the tolerability and efficiency of the new device in the longer term.

Further data concerning comfort, tolerability, effect on the skin in the long term, easiness of self-application by the patient, battery life, and potential economic concerns are beyond the aim of this acute study and need to be assessed by new trials.

However, the principle idea behind the innovative device seems to be an important step concerning the development of “intelligent”, self adjusting compression systems making compression therapy more consistent, safer, and more efficient.

Improvement of the venous pump in patients with chronic venous insufficiency by using inelastic compression devices applied with high pressure seems to be an important detail concerning better understanding of compression therapy and should be emphasised in the next, updated version of the ESVS guidelines.<sup>17</sup>

## CONCLUSIONS

The tests performed for a short time in an experimental setting showed that the new compression device is able to recognise body position using an incorporated accelerometer and to adjust compression pressure to different body positions. The new compression device is significantly more effective than elastic stockings in improving the impaired venous pump, and it is well tolerated and comfortable, at least when evaluated in the acute experiment.

## ACKNOWLEDGEMENT

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## CONFLICTS OF INTEREST

None.

## FUNDING

None.

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