An Innovative Compression System Providing Low, Sustained Resting Pressure and High, Efficient Working Pressure

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An innovative compression system providing low, sustained resting pressure and high, efficient working pressure

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Introduction

Chronic venous insufficiency (CVI) can cause considerable morbidity and reduced quality of life.[1] Compression therapy, such as bandages and stockings, is the cornerstone and golden standard in the prevention and treatment of CVI today.[2] It is also shown that compression used after the healing of ulcers, reduces the rate of recurrence.[3] It has been found that compression products with a stiff, non-elastic material, are essential for an improved haemodynamic effect, indicating that low resting pressure and high working pressure is vital, in order to achieve the most effective and well tolerated compression treatment.[4] However, one great challenge is that by applying a stiff bandage, either as a single component or as a part in a multi-component product, one always adds, a not so easily quantified, resting pressure. In order to achieve the most effective treatment it is easy to apply the bandage in a too tight and uneven manner, often resulting in painful resting pressures.[4] In earlier studies, it has been shown that common for todays practice is that the compression treatment is dependent on the applier and that only about 10% of the healthcare personnel managers to apply a pre-defined target bandage pressure.[5] It has also been shown that the applied pressures decrease in effectiveness, only after a couple of hours, due to *e.g.* oedema reduction, resulting in poor compression treatment over time.[6]

Aim

The goal is to find a method to provide a well-defined resting pressure and a method that increases the working pressure without changing the pre-defined resting pressure, as well as maintaining the pressure over time.

Materials and Methods

First, an elastic compression bandage (Lundatex® medical by PressCise) providing and maintaining a certain pressure level was applied on the leg. The bandage is based on Laplace's law, where the pressure is a product of the force, times the overlap, times the curvature. The bandage is provided with visual guidelines for correct stretch per each turn and correct overlap. Due to the specific elastic properties in the material the force is adjusted to the changes in curvature when the guidelines are followed. This results in a well-defined pressure, with minimal variability. Several patches (PressPatch™ by PressCise AB) made in a hook and loop material and with an optimal shape, were attached over the elastic bandage, creating a multicomponent compression system (Lundatex® system by PressCise AB). The patches adhere directly to the bandage material without any force being added; hence there is no increase of resting pressure. In the front of the leg a special patch was added (FixPatch™ by PressCise AB). This patch can be opened easily *e.g.* every morning, in order to maintain the pressure level over time. In one pilot-study interface pressures were measured on point B1 and C on patients with severe venous reflux in the great saphenous vein (CEAP C2-C5), during lying and standing (n=18). Three consecutive measurements where done: 1) the elastic bandage applied to the leg with a pressure of 20 mmHg, 2) the elastic bandage applied to the leg with a pressure of 30 mmHg and 3) after attaching the stiff patches to the elastic bandage. In a second pilot-study the pressure was measured on one healthy volunteer at B1, over seven days. Measurements were taken in supine, at dorsal flex and standing position, twice a day. The pressure-measuring device used was PicoPress® (by Microlab Italia).

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Conflict of interest: two of the authors have commercial interest to declare. Josefin Damm and Torbjörn Lundh are co-inventors of the patches. The authors are also co-founders of the start-up company PressCise AB.

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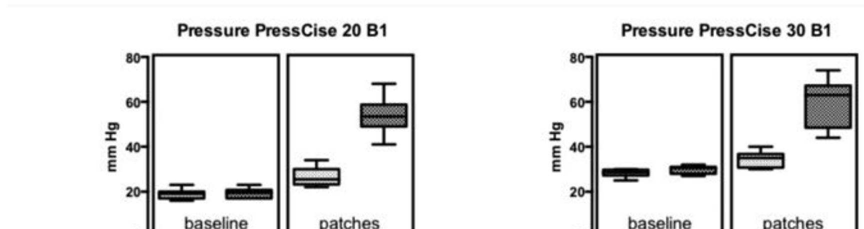
Results

The elasitc bandage provides a well-defined pressure, independent of placement or position. The patches add the stiffness to the underlying material and increase only the working pressure. With the patches, resting pressure is close to the same pressue as before, however working pressure increases significantly. As expected, there were a significant drop of working pressure in the evening day one in the 2nd pilot-study, due to some odema reduction. The correction of the FixPatch™



Pressure PressCise 20 B1

	baseline supine	baseline standing	patches supine	patches standing
Minimum	16.00	17.00	22.00	41.00
25% Percentile	17.00	17.00	23.25	49.00
Median	19.00	19.50	25.50	53.50
75% Percentile	20.00	20.75	30.00	58.75
Maximum	23.00	23.00	34.00	68.00
Mean	18.88	19.25	26.50	53.88
Std. Deviation	2.232	2.188	4.106	8.079
Std. Error of Mean	0.7892	0.7734	1.452	2.856

Pressure PressCise 30 B1

	baseline supine	baseline standing	patches supine	patches standing
Minimum	25.00	27.00	30.00	44.00
25% Percentile	27.25	28.00	30.75	48.50
Median	28.50	30.50	35.00	63.00
75% Percentile	29.75	31.00	36.75	67.25
Maximum	30.00	32.00	40.00	74.00
Mean	28.25	29.75	34.50	60.38
Std. Deviation	1.669	1.832	3.464	10.82
Std. Error of Mean	0.5901	0.6478	1.225	3.826

Figure 1. Pressure measurements on B1, in supine (resting) and standing position with the bandage providing 20 mmHg and 30 mmHg (baseline) and pressure measurements in supine and standing position with the patches added over the bandage (patches). (n=18).

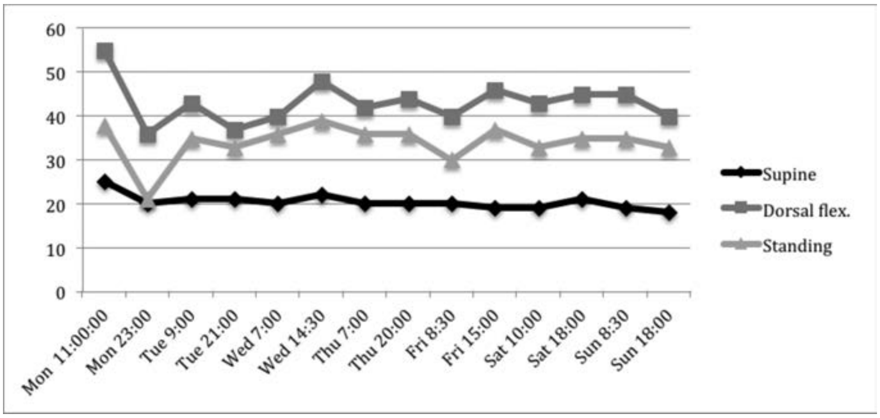


Figure 2. Pressure measurement over seven days, on one subject. Correction of the front patch (FixPatch™) was done daily, before bed rise

each morning, however, maintained the working pressure level over seven days.

Conclusions

The presented device is of considerable practical interest in order to achieve a quantified compression treatment. It may also be especially essential for those patients who should have a low controlled resting pressure, as *e.g.* patients with mixed arterial venous disease and for whom hemodynamically active pressures are desirable as soon the patient is active. The easy way to maintain the pessure level over time may also be of great benefit for self-management.

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