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A new compression stocking with well-defined pressure—a randomized controlled pilot study

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Abstract

Background: To evaluate an innovative class I compression stocking with predetermined uniform pressure in comparison to a graduated class III compression stocking system, regarding edema reduction, interface pressure, and patient comfort.
Method: Twenty-five patients with chronic venous disease, were randomized: 12 to investigational stocking, 13 to comparator stocking. Data collected at baseline and after 14 days.
Results: Edema was significantly equal reduced to follow-up; mean −129.0 cm^3 (SD 105; $p = .004$, Class I) and −223.7 cm^3 (SD 120; $p = .002$, Class III), respectively. The investigational stocking lost significantly less compression pressure than the comparator stocking ($p \leq .013$). Participants in both groups perceived significant improvement regarding leg heaviness, leg swelling, and feelings of tightness and tingling ($p \leq .016$).
Conclusion: The innovative investigational class I stocking appears to offer similar edema reduction and benefits to the comparator class III stocking. However, a larger and prolonged study is required. The study was registered in the ISRCTN-registry, ISRCTN17356077, https://www.isrctn.com/ISRCTN17356077.

Keywords

Chronic venous disease, comfort, compliance, compression, symptom relief

Introduction

Lower leg edema is a multifactorial condition that affects patients with various conditions, with the dominant cause being chronic venous disease. Untreated lower leg edema can result in a range of cutaneous complications such as eczema, inflammation, hemosiderin deposits, and leg ulcers. Leg ulcers have a high morbidity resulting in economic strain both at personal and state levels, are often painful, debilitating and difficult to treat, and greatly reduce patients' quality of life.[1] Treatment is aimed at the underlying cause, but almost regardless of the pathophysiology, compression therapy forms a cornerstone in both the prevention and treatment of symptoms related to edema of the lower extremities.[2] Compression can be achieved in a number of ways including the use of elastic or inelastic bandages, adjustable wraps, multicomponent bandages, pneumatic compression devices, and compression stockings.

Standard compression stockings apply the greatest pressure at the ankle with a gradual decrease in pressure proximally and are available in different compression classes according to the exerted pressure applied at the ankle region.[3] There is no single standard compression class system used worldwide, but the European standard (CEN/TR 15831:2009) refers to; over the counter (<15 mmHg), class I (15–21 mmHg), class II (23–32 mmHg), class III (34–46 mmHg), or class IV (>49 mmHg).

Compression stockings used for treating chronic venous disease often need to exert a minimum of 20 to 30 mmHg of pressure at the ankle to be effective, and higher-grade compression stockings (30 to 60 mmHg) may be

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required for more severe cases of chronic venous disease or for patients with chronic lymphedema.[4]

It is worth noting that the pressure exerted by compression stockings is affected by several factors including elasticity and stiffness of stocking material, movements and activities of the wearer, the size and shape of the wearer's legs, and the various and changing circumference of the leg during treatment.

To solve these problems, various textile materials and stocking models have been marketed and there is a wide range of different sizes and shapes of stockings as well as custom-made compression stockings (also known as "made to-measure") available today. Despite this, many ready-made standard compression stockings do not properly fit the majority of patients using current standardized measuring methods,[5] and even custom-made or perfectly fitted standard stockings cannot accommodate changes in leg circumference that occur as edema decreases/increases.

Furthermore, since standard stocking classes focus on exerted pressure at the ankle region, they usually cause uneven pressure (e.g., excessive or peak focal pressure) around and along the lower extremities due to differing leg morphologies and anatomical structures. This may cause serious side effects, including ischemia, necrosis, and even ulcerations, especially over bony prominences in elderly people with thin and fragile skin.[6,7] Another shortcoming of standard compression stockings is non-compliance. This is mainly due to difficulties experienced in donning and doffing the stockings; the higher the compression pressure, the more difficult this is.[8] Therefore, in this study the aim is to evaluate a new innovative class I compression stocking (20 mmHg) that has predetermined uniform pressure, regarding edema reduction and interface pressure in comparison to a graduated class III compression stocking system (40 mmHg). Another aim was to evaluate the stockings regarding comfort, functionality, compliance, and symptom relief.

Material and methods

Study design

A two-arm prospective randomized controlled non-blinded pilot study was used. The study was registered in the ISRCTN-registry, ISRCTN17356077.

Study setting and population

The study was conducted in Sweden between October 2019 and January 2021. Participants were recruited from a hospital dermatology department, municipal healthcare within the hospital's admission area, and through advertisements published on websites and in printed press.

The sample size was based on a power analysis. The sample size was determined on the assumption that the comparator stocking has a variance of 20% of its efficiency (volume reduction) and that the investigational stocking has an efficiency that is one third better (i.e., 33%) than the comparator stocking with the same variance of 20%. The assumption that the investigational stocking has higher efficiency is based on the fact that, unlike the comparator stocking, it provides uniform pressure along the entire leg, that is, a higher or equivalent pressure over the calf,[9,10] and that, thanks to its innovative knitting, it maintains the predefined pressure over time. For a test with power 0.9 and a t2 test for a hypothesis test with the null hypothesis that there is no difference between these stockings, following Matlab command was used:

$$n = \text{sampsizepwr}\,(\text{'t2'}, [1\ 0.2], 1.33, 0.9, [])$$

This gives nine participants per group. Participants were considered eligible for inclusion if they were (1) adults (≥18 years) with chronic venous disease class C3 (edema) or C4 and C5 (with edema),[11] (2) had a leg circumference of 20 – 65 cm at the narrowest and widest place, respectively, and (3) an ankle brachial index (ABI) of >0.8. Patients with lipedema, diabetes, or congestive heart failure were excluded.

The screening process for eligibility was performed consecutively in two stages, please see Figure 1. In an initial screening, patients were informed about the study by phone and were asked about inclusion and exclusion criteria. Patients, who met the inclusion criteria (n = 29) were then referred to a second screening that comprised a physical evaluation (conducted by MF) that included (1) screening for objective signs of edema and chronic venous disease, and (2) ABI measurements. At this stage, another four patients were excluded as they had no objective signs of edema.

In order to have a margin for dropouts, 25 patients were randomized into two groups; the investigational stocking group (n = 12) and the comparator stocking group to follow-up (n = 13).

Procedure

The study was carried out over fourteen consecutive days with two study visits, a baseline visit and randomization, and a follow-up visit.

Baseline visit and randomization. At baseline each participant filled in the first part of a questionnaire collecting their previous experience of compression stockings and perceived symptoms of edema (Table 1). The first author (UK) gathered background data (age, gender, ABPI, weight, and height), information about physical activity and reason for eventual previous compression therapy. A visual skin assessment of the participant's skin was performed. If both

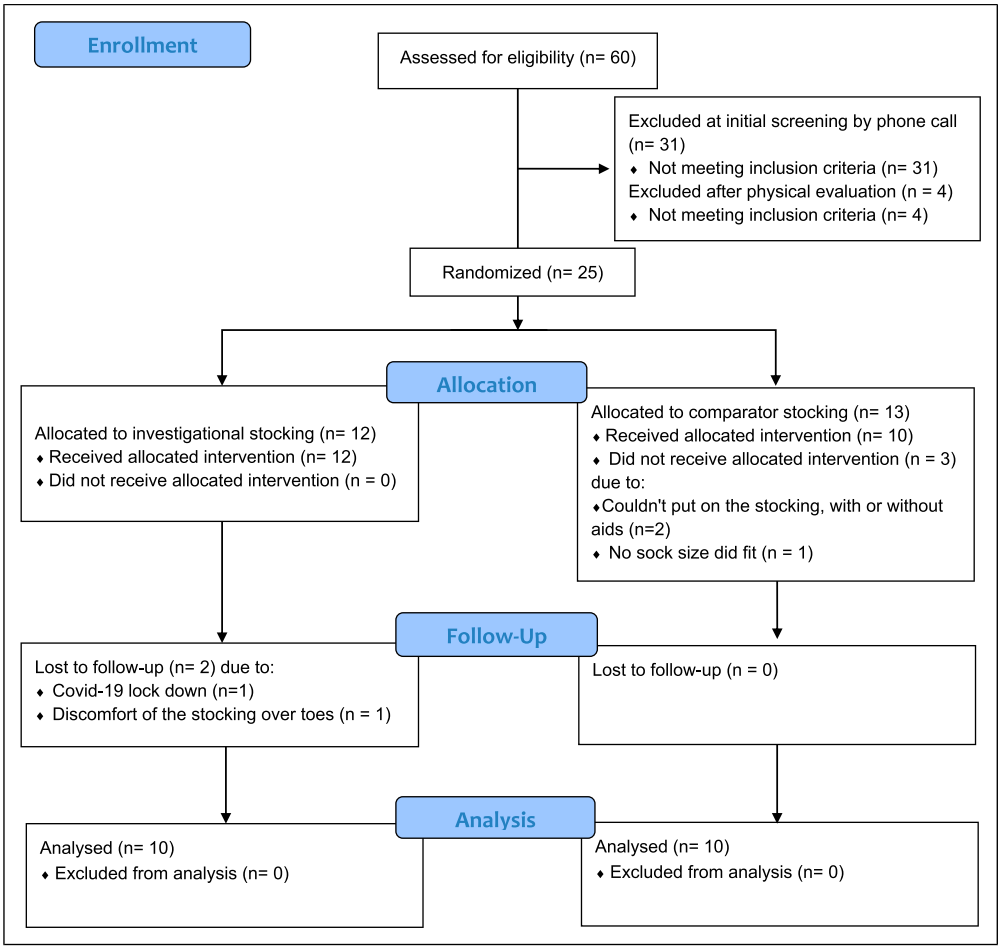

Figure 1. Consolidated Standards of Reporting Trials (CONSORT) flow diagram for subjects involved in the trial. The patients' progress through the trial is indicated in the diagram, including final number (n) values for each study group.

legs were equally diseased, the right leg was assessed. If not, the most severely diseased leg was assessed.

After the visual skin assessment, each patient was randomly assigned to either the investigational stocking or the comparator stocking in a 1:1 ratio using a randomization list. The list had been generated by a person outside the research group and was done using a random formula in Excel. To conceal the randomization sequence, sequentially numbered, sealed opaque envelopes were used. Which group each participant was randomized to was only known once the envelope was opened. The allocated stocking was not blinded from the researcher or the patients.

After randomization, baseline measurements of the leg circumferences were carried out by the principal investigator. The stocking size was selected based on leg length, circumference measurements (ankle and calf), and shoe size. The stocking was then put on the selected leg, whereafter the interface pressure between the stocking and skin was measured both in supine position and in standing position.

The participants were educated in how and when to wear their assigned stockings, including how to don and doff them and they were instructed to use them for two consecutive weeks. Patients were also instructed to remove their stockings in the case of pain developing. They received two pairs of stockings so they could wash the used pair when necessary.

The investigational stocking. The investigational stocking, Lundatex® stocking from PressCise AB, is a single-layer, knee-high compression stocking with closed toes. The stocking is based on the same technical principle as the previously developed Lundatex® medical elastic compression bandage[7,12] and delivers a uniform pressure over the leg of 20 ± 2 mmHg (corresponding to compression class I) regardless of leg size and shape or changes in leg circumference due to an increase or decrease in edema. The stocking is made from 77% polyamide and 23% elastodiene and is latex-free. Fittings are carried out using three measurements: the length (cm) from ground to just below the knee, the ankle and calf circumference (cm), and shoe size.

Table 1. The International Compression Club Compression Questionnaire[14]—patient part, which was used in the study. Score 0 corresponds to "not at all" or "not able at all" and score 10 corresponds to "a lot" or "completely able."

Filled out at baseline visit	Subsection 1
	Physical functioning without wearing compression, that is, ability to [score 0 – 10]:
	- ability to move the ankle
	- to walk
	- to partake in social activities
	Disease-related symptoms [score 0 – 10]
	- pain?
	- loss of muscle strength?
	- heaviness?
	- swelling?
	- tight skin?
	- tingling?
	- leakage of fluid (through skin)?
Filled out at follow-up visit	Subsection 2
	Physical functioning in relation to allocated compression, that is, ability to [score 0 – 10]:
	- to move the ankle
	- to walk
	- to partake in social activities
	- to wear clothes
	- to wear shoes
	Complications of compression [score 0 – 10]:
	- skin irritation?
	- tender spots?
	- damage of skin?
	- itching?
	- warmth?
	- throbbing?
	- stockings sliding down?
	- local swelling?
	- bulky feeling?
	- too tight feeling?
	Disease-related symptoms [score 0 – 10]
	- pain?
	- loss of muscle strength?
	- heaviness?
	- swelling?
	- tight skin?
	- tingling?
	- leakage of fluid (through skin)?
	Application and removing of compression
	-to what extent was it possible for you to put on your compression stockings yourself? [score 0 – 10]
	- did you need assistance to put on your stockings? [yes/no]
	- what kind of help did you need? [assistance of a person/aids]
	-to what extent was it possible for you take off your compression stockings yourself? [score 0 – 10]
	- did you need assistance to take off your stockings? [yes/no]
	- what kind of assistance did you need? [help from a person/use of aids]
	Compliance
	During the last 2 weeks, how many days did you wear your stockings? [1–14 days]
	If you did not use the stockings every day, what was your reason for this? [open ended]

The stocking can be worn day and night due to the low pressure it provides.

The comparator stocking. The comparator stocking selected was a double-layer, knee-high medical compression stocking system (Actico® UlcerSys kit from Lohmann and Rauscher GmbH and Co.). The liner stocking has a closed toe and provides a compression pressure of 10 mmHg and the overstocking, that has an open toe, adds an additional compression pressure of 30 mmHg. The two layers together exert a pressure of about 40 mmHg in the ankle area, corresponding to compression class III. The two-component

system is aimed to facilitate donning and doffing the stocking. The liner is made from 70% polyamide and 30% Lycra and the overstocking is made from 65% polyamide and 35% Lycra. Fittings are carried out using three measurements: the widest point of the calf, 2–3 cm above the ankle, and 2–3 cm below the popliteal fossa to the ground. Due to the high resting pressure, the overstocking must be removed at night. The liner should be worn day and night.

Follow-up visit. At the follow-up visit, 2 weeks after inclusion, participants were first asked to fill out the second part of the questionnaire (Table 1). Thereafter, the interface pressures under the stockings were taken, following the same procedure as that used during the baseline visit. After removing the stockings, leg circumference was measured, and a visual skin assessment was performed and thereafter the study was ended.

Outcome assessment

Primary outcome

Edema reduction. Circumferential measurements were taken to measure leg edema (cm) in supine position, at 4-cm intervals starting at a predetermined and well-defined zero point using novel designed measuring tape (PeriKit, from Just a New Health s.à.r.l.) (Figure 2). Special pillows were used to relieve the leg from pressure during the measurement. In all cases, measurements of leg circumference were also performed at two defined locations: B1 (approximately

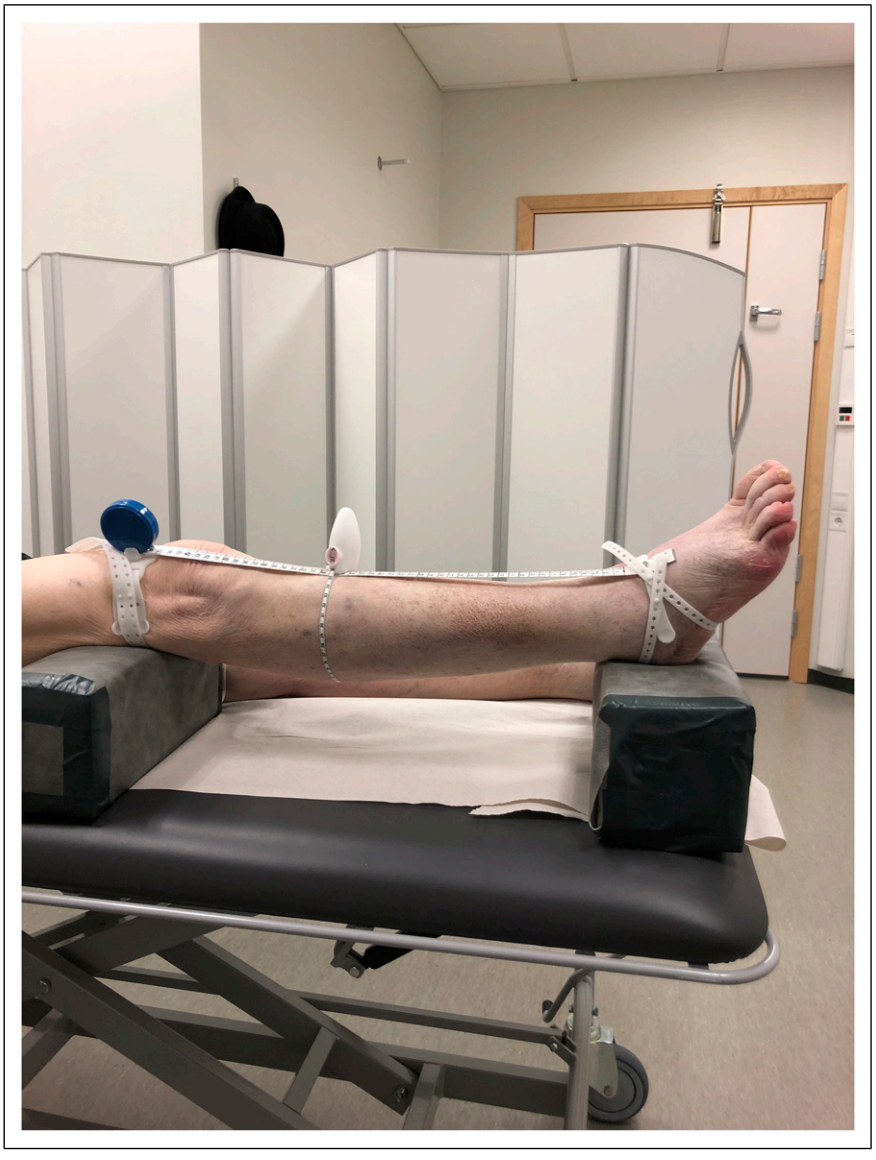

Figure 2. The measurement tape with a predetermined and well-defined zero point.

10–15 cm proximal to the medial malleolus) and C (maximum girth of the calf). Length of the leg was measured from the sole of the foot to behind the knee.

Volume was calculated using the formula:
$V = \frac{1}{3} \cdot \pi \cdot h \cdot (a^2 + a \cdot b + b^2)$.

Secondary outcome

Interface pressure. The interface pressure (mmHg) of the stocking was registered using the pneumatic pressure measuring device, PicoPress® (Microlab Electronica, s.a.s.) in both supine and standing position. According to the manufacturer's technical manual, the PicoPress® has a precision of ±3 mmHg. The repeatability full scale (FS) error for PicoPress sensors has been shown to be 0.73% FS.[13] Two pressure sensors were placed on the two defined sites B1 and C.

Patient comfort, functionality, compliance, and symptom relief. To evaluate comfort, functionality (e.g., donning and doffing), compliance, and symptom relief, a modified version of the International Compression Club Compression Questionnaire patient part was used (ICC-CQ-P)[14] (Table 1).

The majority of answer options consisted of linear rating scales, ranging from 0 to 10. Zero corresponded to "not at all" or "not able to at all" and ten corresponded to "a lot" or "completely able." Answer options regarding application and removing the stockings were "yes" or "no." If the answer was "yes" they were asked to define what kind of help or system they needed. Finally, participants filled out how many days they had used the stockings during the study period.

Statistics and analysis

Imputation of leg circumference data at B1 and C was done for two participants where this data was missing, see Appendix 1. For comparison between groups, the Fisher's non-parametric test was used for continuous variables and the Fisher's non-parametric permutation test was used for matched pairs.

Statistical per-protocol analysis was performed in SAS 9.4 by SAS Institute Inc., Cary, NC, USA and the level of significance was set at $p \leq .05$.

Results

Patient characteristics

Of the 25 participants who were randomized, five were lost to follow-up: two in the investigational stocking group and three in the comparator stocking group (Figure 1). The per-protocol analysis included 20 participants: 10 in each group. There was no significant difference between these two study groups in terms of age, gender, BMI, height, weight, shoe size, or leg circumference at B1 (Table 2). Three participants in each group were gainfully employed and the remaining were pensioners. Most participants were physically active (8 in the investigational group and 9 in the comparator group).

Primary outcome—Edema reduction

Both the investigational stocking and the comparator stocking significantly reduced edema from baseline to follow-up; mean −129.0 cm^3 (SD 105; $p = .004$) and −223.7 cm^3 (SD 120; $p = .002$), respectively (Table 3 and Figure 3). There was no significant difference in volume reduction between the two groups (mean −94.6 cm^3, $p = .075$).

There was a significant reduction in the leg circumference in both groups; the investigational stocking at point B1 was −1.2 cm (mean, SD 1.0; $p = .010$) and at point C was −1.3 cm (mean, SD 0.8; $p = .002$) versus the comparator stocking at point B1, which was –2.1 cm (mean, SD 2.3; $p = .010$) and at point C was –1.6 cm (mean, SD 1,4; $p = .002$). There was no significant difference in circumference reduction between the two groups at point B1 and at point C.

Table 2. Baseline demographic characteristics of patients.

	Investigational stocking		Standard stocking			
Variable	*n* =	Mean (SD)	*n* =	Mean (SD)	*p*-value	Difference between groups Mean (95% CI)
Age	10	71.4 (10.7)	10	66.6 (9.2)	0.30	−4.80 (−14.00; 4.40)
BMI	9	31.2 (8.7)	10	27.0 (3.4)	0.20	−4.23 (−10.61; 2.11)
Height (cm)	9	167.6 (9.7)	10	169.3 (11.0)	0.74	1.74 (−8.50; 12.00)
Weight (kg)	9	86.8 (20.5)	10	77.4 (11.7)	0.25	−9.38 (−25.40; 6.40)
Shoe size	10	40.8 (2.9)	10	40.2 (3.0)	0.69	−0.600 (−3.400; 2.200)
Leg circumference point B1 (cm)	10	29.6 (4.0)	10	29.6 (3.9)	0.99	−0.040 (−3.800; 3.700)

Table 3. Baseline and follow-up values (mean SD) within-group and between-groups comparison of leg volume, sock compression, and leg circumference.

	Investigational stocking class I			Comparator stocking class III				
Variable	*n* =	Mean (SD)	*p*-value within group	*n* =	Mean (SD)	*p*-value within group	*p*-value between groups	Difference between groups Mean (95% CI)
Leg circumference point B1 (cm):								
Baseline	10	29.6 (4.0)		10	29.6 (3.9)			
Follow-up	10	28.4 (3.9)		10	27.5 (3.8)			
Change Baseline—Follow-up	10	−1.22 (1.00)	0.0098	10	−2.08(2.29)	0.0020	0.35	−0.86 (−2.52; 0.50)
Leg circumference point C (cm):								
Baseline	10	42.2 (4.2)		10	40.2 (4.7)			
Follow-up	10	40.9 (4.3)		10	38.6 (5.3)			
Change Baseline—Follow-up	10	−1.31 (0.77)	0.0020	10	−1.65 (1.37)	0.0020	0.59	−0.34 (−1.40; 0.60)
Leg volume (cm^3):								
Baseline	10	3097 (711)		10	2889 (621)			
Follow-up	10	2968 (699)		10	2665 (682)			
Change Baseline—Follow-up	10	−129.0 (105)	0.0039	10	−223.7 (120)	0.0020	0.075	−94.6 (−202.3; 10.1)
Compression pressure (mmHg) point B1 in rest:								
Baseline	10	23.3 (1.6)		10	41.9 (7.4)			
Follow-up	9	20.7 (1.7)		10	33.3 (8.4)			
Change Baseline—Follow-up	9	−2.56 (1.88)	0.0078	10	−8.60 (2.88)	0.0020	0.0002	−6.04 (−8.50; −3.67)
Compression pressure (mmHg) point C in rest:								
Baseline	10	22.6 (1.5)		10	33.3 (5.1)			
Follow-up	9	20.1 (2.1)		10	27.6 (4.3)			
Change Baseline—Follow-up	9	−2.33 (1.32)	0.0078	10	−5.70 (3.27)	0.0020	0.013	−3.37 (−5.80; −1.00)
Compression pressure (mmHg) point B1 on standing:								
Baseline	9	25.2 (2.0)		9	46.0 (6.4)			
Follow-up	9	22.2 (1.4)		9	37.3 (8.0)			
Change Baseline—Follow-up	8	−3.00 (1.31)	0.0078	9	−8.67 (4.21)	0.0039	0.0025	−5.67 (−9.00; −2.33)
Compression pressure (mmHg) point C on standing:								
Baseline	10	25.0 (1.6)		9	38.9 (5.1)			
Follow-up	9	22.8 (2.7)		9	30.7 (4.8)			
Change Baseline—Follow-up	9	−2.11 (1.83)	0.0078	9	−8.22 (2.44)	0.0039	0.0004	−6.11 (−8.25; −4.00)

Secondary outcomes

Interface pressure. The investigational stockings interface pressure at location of B1 was in supine position 23.3 mmHg (mean, SD 1.6, range 21 – 26) and when standing 25.2 mmHg (mean, SD 2.0, range 21 – 27) at baseline. Corresponding figures for the comparator stocking were in supine position 41.9 mmHg (mean, SD 7.4, range 30 – 52) and standing 46.0 mmHg (mean, SD 6.4, range 37 – 53) (Table 3, Figure 4).

The interface pressure was significantly reduced for both stockings from baseline to follow-up, both at point B1 and C and when measured in both supine and standing position (Table 3, Figure 4); the investigational stocking at most in mean 3.0 mmHg (SD 1.3; $p = .008$) and the comparator stocking at most 8.7 mmHg (SD 4.21; $p = .004$).

The investigational stocking lost significantly less compression pressure than the comparator stocking regardless of body position ($p \leq .013$) (see Table 3).

Compliance. All participants had used the stockings during the entire study period (14 days), except for one participant in the investigational stocking group who had used the stockings for 13 of the 14-day study period (the stockings did not match their outfit on 1 day).

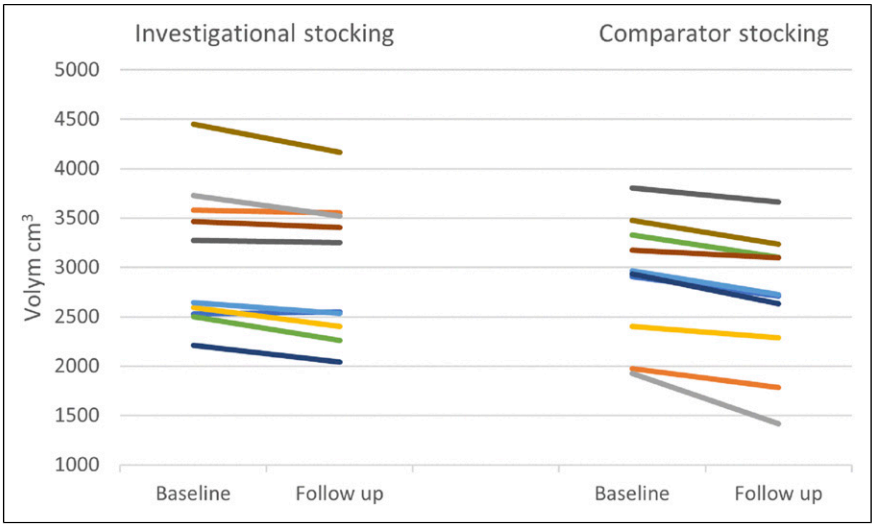

Figure 3. The leg volume (cm^3) at baseline and at follow-up, for the patients randomized to the investigational class I stocking and the comparator class III stocking.

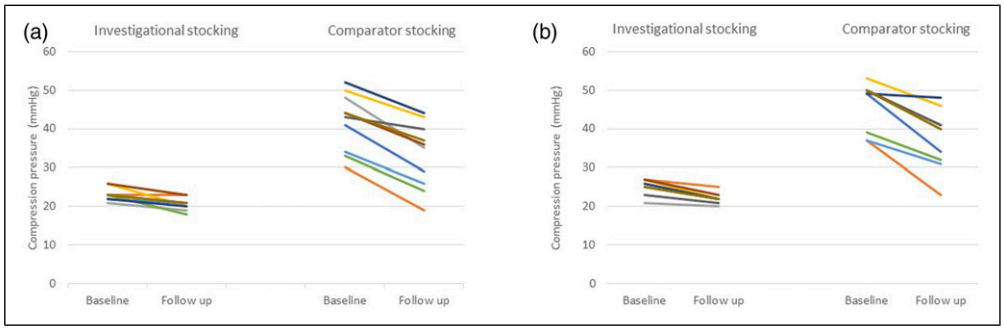

Figure 4. The compression interface pressure at the B1 location in resting (a) and standing position (b), at baseline and at follow-up, for the patients randomized to the investigational class I stocking and the comparator class III stocking.

Physical functioning and disease-related symptoms. Participants in both groups perceived significant improvement with regard to leg heaviness, leg swelling, a tight skin feeling, pricking and tingling (Table 4). The participants in the investigational stocking group also perceived improvement with regard to ankle mobility, walking ability, and pain. Over 70% in both groups perceived that the stocking could be used together with their clothes and shoes. There were no statistically significant differences between the groups with regard to self-perceived physical functioning and symptom improvement.

Application and removing of the compression stockings. One participant wearing the investigational stockings required assistance with donning versus two participants wearing the comparative stocking. Two participants needed assistance with doffing versus four participants in the comparator group. The remaining participants were able to don and doff their stockings without assistance.

Complications of compression. Complications of wearing stockings were rated by the patients (Figure 5). Skin irritation, tender spots, damage to skin, itching, and local swelling caused by the compression stockings were rated by both groups as having a mean score of less than three on a ten-point scale. There were no significant differences between the groups. Five participants wearing the investigational stockings experienced complications rated six or higher; these included tender spots, damage to skin, warmth, itching, or local swelling. One participant experienced the comparator stocking causing tender spots, skin irritation, and was warm to wear. Another participant in this group experienced that the stockings were sliding down, and another participant experienced that the stockings were bulky. (Figure 5).

Table 4. Baseline and follow-up values (Mean SD) within-group and between-groups regarding mobility and disease-related symptoms measured with a questionnaire which consisted of linear rating scales, ranging from 0 to 10 points.

	Investigational stocking class I			Comparator stocking class III				
Variable	*n* =	Mean (SD)	*p*-value within group	*n* =	Mean (SD)	*p*-value within group	*p*-value between groups	Difference between groups Mean (95%CI)
Ankle mobility:								
Baseline	10	7.90 (2.48)		10	8.28 (3.29)			
Follow-up	10	9.48 (0.70)		10	8.40 (3.20)			
Change Baseline—Follow-up	10	1.58 (2.00)	0.016	10	0.120 (1.974)	0.88	0.13	−1.46 (−3.32; 0.40)
Walking ability:								
Baseline	10	8.69 (1.26)		8	8.95 (1.57)			
Follow-up	10	9.64 (0.35)		8	9.49 (1.02)			
Change Baseline—Follow-up	10	0.950 (1.192)	0.047	8	0.538 (1.422)	0.44	0.53	−0.413 (−1.675; 0.867)
Social activity:								
Baseline	10	9.31 (0.88)		10	8.52 (1.97)			
Follow-up	10	9.75 (0,27)		10	9.52 (1.25)			
Change Baseline—Follow-up	10	0.44 (0.86)	0.19	10	1.00 (1.90)	0.19	0.43	0.56 (−0.840; 2.000)
Pain:								
Baseline	10	2.56 (2.02)		10	2.68 (2.70)			
Follow-up	10	0.350 (0.321)		10	1.64 (2.51)			
Change Baseline—Follow-up	10	−2.21 (1.99)	0.0078	10	−1.04 (3.88)	0.43	0.45	1.17 (−1.58; 4.05)
Muscle strength:								
Baseline	10	3.36 (2.17)		8	2.44 (2.61)			
Follow-up	10	0.390 (0.363)		9	0.478 (0.714)			
Change Baseline—Follow-up	10	−2.97 (2.15)	0.012	8	−1.90 (2.28)	0.063	0.33	1.07 (−1.20; 3.22)
Leg heaviness:								
Baseline	10	5.37 (2.75)		10	5.30 (3.05)			
Follow-up	10	0.450 (0.479)		10	1.62 (2.41)			
Change Baseline—Follow-up	10	−4.92 (2.64)	0.0039	10	−3.68 (3.17)	0.012	0.37	1.24 (−1.57; 3.92)
Leg swelling:								
Baseline	10	7.30 (1.85)		9	8.04 (1.26)			
Follow-up	10	1.16 (1.10)		10	1.32 (2.46)			
Change Baseline—Follow-up	10	−6.14 (2.41)	0.0020	9	−6.58 (2.48)	0.0039	0.71	−0.438 (−2.825; 1.920)
Tight-feeling skin:								
Baseline	9	5.07 (3.51)		10	4.70 (3.21)			
Follow-up	10	0.480 (0.607)		10	0.950 (1.430)			
Change Baseline—Follow-up	9	−4.59 (3.25)	0.016	10	−3.75 (2.60)	0.0039	0.54	0.839 (−2.000; 3.733)
Pricking and tingling:								
Baseline	10	4.99 (2.51)		10	4.90 (3.21)			
Follow-up	10	0.500 (0.609)		10	1.32 (1.87)			
Change Baseline—Follow-up	10	−4.49 (2.29)	0.0020	10	−3.58 (2.54)	0.0078	0.41	0.910 (−1.360; 3.180)

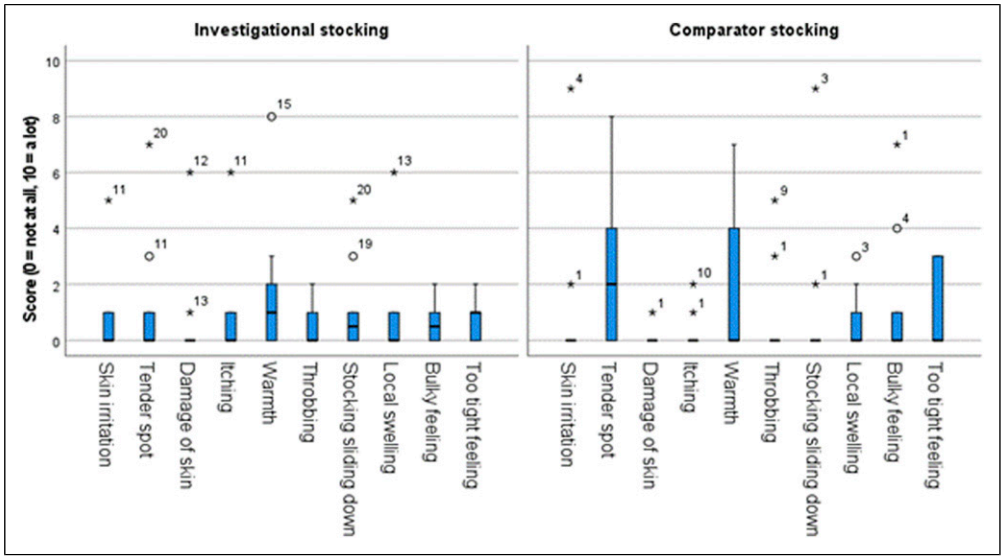

Figure 5. The participants' ratings of complications of the compression provided by the investigational class I stocking and the comparator class III stocking (Score 0 = "not at all" – 10 = "a lot").

Discussion

The study shows that the investigational class I stocking with uniform pressure led to a significant edema reduction, equivalent to treatment with the graduated comparator compression class III stocking. Also, disease-related symptoms reported by participants, such as heaviness, swelling, tight-feeling skin, prickling, and tingling, were equally improved in both groups. The results are like other studies where compression stockings with a pressure ranging from 15 to 32 mmHg have proven to be effective in relieving symptoms in patients with chronic venous disease.[15,16] However, the result is interesting as the investigational stocking provides a much lower compression pressure than the comparator stocking, which is a finding that may also have clinical significance. Being able to achieve edema reduction with low pressure is of value for patients who have concomitant impaired arterial circulation or severe neuropathy.[17] The investigational stocking can be an alternative in these cases. One reason why the investigational class I stocking reduced edema as much as a class III stocking may be the uniform pressure, which is a fact confirmed in this study. The interface pressure over the B1 and C locations in supine position was 23.3 and 22.6 mmHg, respectively. Another reason may be the investigational stocking's ability to follow the curvature of the leg and maintain basically the same pressure regardless of the shape of the leg. Both stockings used in this study saw statistically significantly reductions in interface compression pressure from baseline to follow-up, however, the investigational stocking lost only 2.11 – 3.00 mmHg depending on place measured and if in supine or standing position. Corresponding values for the comparator stocking were between 5.70 mmHg and 8.67 mmHg, which was, in all situations, a statistically significantly larger reduction than the investigational stocking. As PicoPress has a precision of ±3 mmHg, one should interpret these differences with caution. It is, however, a known problem that compression materials lose their ability to exert pressure over time[18,19] and it is interesting to notice that the comparator stocking delivered a huge variation in pressure both at baseline (30–52 mmHg) and at follow-up (Table 3 and Figure 4), while the investigational stocking ranged between 21 and 26 mmHg. The results indicate that the investigational stocking provides a precise pressure independent of the leg size and shape or changes in leg circumference due to an increase/decrease in edema.

The participants in both groups had similar compliance in using the stockings, experience of comfort, and perception of the ability to don and doff them. The participants wearing the investigational stockings also perceived an improvement in ankle mobility, walking ability, and pain. A larger and prolonged study would, however, be necessary to evaluate these possible differences regarding compliance, interface pressure, and edema reduction.

Limitations

The results of this trial should be interpreted with caution due to the study's limitations. Firstly, neither the investigator nor the participants were blinded, which can have contributed to observer bias. Secondly, the study was conducted over a short period of time—only 2 weeks. To evaluate the stockings' ability to maintain compression pressure and reduce edema, the follow-up period should be longer. This would also be advantageous in the evaluation of

compliance and personal perceptions of the assigned stockings. Thirdly, due to the small sample size, these results should be considered suggestive rather than conclusive. Future studies with larger sample sizes are needed to provide additional understandings.

Conclusion

The study demonstrates that the investigational class I stocking seems to offer similar edema reduction and benefits as the comparator class III stocking, and that it delivers well-defined uniform compression pressure over time. A larger and prolonged study is required to further evaluate the investigational stocking's ability to maintain the effect of improving venous insufficiency symptoms and promote compliance of compression therapy.

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Declaration of conflicting interests

The author(s) declared the following potential conflicts of interest with respect to the research, authorship, and/or publication of this article: The author(s) declared the following potential conflicts of interest: The project, financed by Sweden's innovation agency VINNOVA, consisted of two parts: the development of the Lundatex® stocking by PressCise AB and the evaluation of the stocking by our research group. Produced stockings were subsequently used in the study and evaluated independently of the company in this scientific report. Actico® UlcerSys kit from Lohmann and Rauscher GmbH and Co. KG was purchased from project funds and was not provided by the company.

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Ethical statement

Ethical approval

The study was approved by the County Council Ethics Board of Gothenburg, Sweden, Dnr 956-18 and T1126-18 and by the head of departments. All participants gave both oral and written informed consent to their voluntarily participation. They were informed that they could withdraw at any time without explanation and without it affecting their future care. No compensation was paid, but participants could keep their compression stockings.

Guarantor

UK is guarantor.

Contributorship

UK, MF, and CB conceived and designed the study. UK and MF conducted the study and conducted the statistical analysis together with a statistician. All authors contributed to the writing process of the manuscript.

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Appendix 1

Description of data imputation

For two participants in the comparator stocking group, the circumference data for B1 and C from the follow-up visit was missing in the data set. Imputation was used as follow for the missing data:

Participant one. The B1 point on the patient was at a distance of 15 cm from PerKit zero-point. We had data of the circumference measured at level 12 cm and 16 cm: 30.1 cm and 33.9 cm, respectively. The value at 15 cm were therefore estimated to be 33.0 cm.

33.9 cm – 30.1 cm = 3.8 cm
3.8 cm/4 cm = 0.95
33.9 cm – 0.95 cm = 33.0 cm

The C point on the patient was at a distance of 26 cm from PerKit zero-point. We had data of the circumference measured at level 24 cm and 28 cm: 39.7 cm and 40.6 cm, respectively. The value at 26 cm were therefore estimated to be 40.2 cm.

40.6 cm – 39.7 cm = 0.9 cm
0.9 cm /4 cm = 0.225 cm
40.6 cm – (0.225 + 0.225) = 40.2 cm

Participant two. The B1 point on the patient was at a distance of 10 cm from PerKit zero-point. We had data of the circumference measured at level 8 cm and 12 cm: 19.7 cm and 21.6, respectively. The value at 10 cm were therefore estimated to be 20.7 cm.

21.6 cm – 19.7 cm = 1.9 cm
1.9 cm /4 cm = 0.475 cm
21.6 cm – (0.475 + 0.475) = 20.7 cm

The C point on the patient was at a distance of 22 cm from PerKit zero-point. We had data of the circumference measured at level 20 cm and 24 cm: 27.3 cm and 28.7 cm, respectively. The value at 10 cm were therefore estimated to be 28.0 cm.

28.7 cm – 27.3 cm = 1.4 cm
1.4 cm / 4 cm = 0.35
28.7 cm – (0.35 + 0.35) = 28.0 cm.