RANDOMISED CONTROLLED TRIAL

Compression Stocking With 100% Donning and Doffing Success: An Open Label Randomised Controlled Trial

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WHAT THIS PAPER ADDS

Compression garments that do not compress the foot and heel area may represent a relatively simple solution to improving patient's treatment adherence. They are significantly easier to put on (don) and take off (doff) than standard stockings, while providing the same degree of diurnal oedema prevention.

Objective: The aim of this study was to test whether an investigational two layer stocking exerting 27—29 mmHg pressure at the medial supramalleolar level, but without compression in the foot and heel, is easier to put on and take off than a standard stocking of the same compression class (23—32 mmHg), and also to assess the prevention of diurnal oedema with both types of stocking.

Methods: This was an open label randomised controlled trial, which included 47 patients. All participants were at least 65 years of age and suffered from chronic venous disease class C3 — C6 in one leg. The primary end point was donning success; secondary endpoints were doffing success, prevention of diurnal oedema over one day, and the comfort of wearing the stocking. Patients were randomly allocated to one of two groups. Both types of compression stocking were compared in each group for ease of donning and doffing in the manner of a crossover study. Subsequently, patients wore the stocking type assigned to their group for a whole day to evaluate comfort and the effect on diurnal leg volume.

Results: All participants were able to don the investigational stocking unaided, compared with 75% for the standard stocking ($p < .001$). Unaided removal success was 100% with the investigational stocking *vs.* 66% for the standard stocking ($p < .001$). There was no significant difference in leg volume reduction between the study groups after a day of wear. The investigational stocking was also rated as being more comfortable than the standard stocking ($p < .001$).

Conclusion: The investigational stocking, which has no compression in the foot or heel area, is significantly easier to don and doff, with no inferiority in oedema prevention, compared with a standard stocking of the same compression class.

Keywords: Compression free foot and heel area, Compression stocking, Put on (don), Diurnal leg oedema, Take off (doff), Treatment compliance
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INTRODUCTION

Compression therapy has been shown to be clinically effective in the treatment and prevention of a wide range of diseases including chronic venous disease, deep venous thrombosis, post-thrombotic syndrome, post-operative compression, and lymphoedema.[1,2]

However, poor treatment compliance, estimated to be approximately 60%,[3—7] represents the main shortcoming of compression stocking therapy. Difficulty in donning and doffing stockings is the main reason for this, especially for patients with reduced grip strength and/or arthritis. Further reasons for non-compliance include obesity, pruritus, skin irritation, skin lesions, a feeling of constraint, a feeling of heat build up, garment sliding, and leg strangulation.[8—10]

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Standard compression stockings are knitted with a graduated pressure profile, with the highest interface pressure exerted over the supramalleolar area gradually decreasing towards the knee and are designed to counteract the increased venous hypertension caused by gravity when standing.

Anatomically, the circumference of the heel is 1.5 times larger than the circumference of the supramalleolar area. Consequently, when donning or doffing a compression stocking, overcoming the heel requires the most effort.[11]

The aim of this study was to confirm the superior ease of use (donning and doffing) and comfort of an investigational medical compression stocking that omits compression in the foot and heel section and is therefore easier to put on and take off, while preserving the physical properties and clinical effectiveness of a standard compression stocking in terms of preventing diurnal oedema.[12]

MATERIAL AND METHODS

Study design

A single centre, open label, randomised controlled trial (RCT) was conducted comparing the investigational two layer compression stocking, which exerts 27—29 mmHg pressure at the medial supramalleolar level, graduated from the ankle to the calf, but without compression in the foot and heel, with a standard compression stocking of the same size and compression class (23—32 mmHg).

The study was carried out over three consecutive days, with four study visits (V1 — V4). Patients provided written informed consent and then observed a washout period of two days without any compression therapy. Each patient was randomly assigned to either the investigational compression stocking or the standard compression stocking. All patients evaluated both stockings for ease of donning and doffing in the manner of a crossover study, testing the stocking from their assigned study group first (investigational or standard). Patients then wore the stocking from their assigned group for a whole day (Fig. 1).

Recruitment and data collection were conducted from inpatients and outpatients of the Department of Dermatology, University Hospital of Zurich, from January 2018 to June 2018. Eligible patients had to be at least 65 years old with one leg showing chronic venous disease class C3 — C6 according to the CEAP classification.[13] The clinical diagnosis had to have been confirmed by duplex ultrasound. Patients had to have superficial truncal or deep venous reflux $>$ 0.5 seconds over several vein segments or chronic deep vein occlusion. C3 was diagnosed when patients had pathological findings on duplex ultrasound and leg oedema. Patients

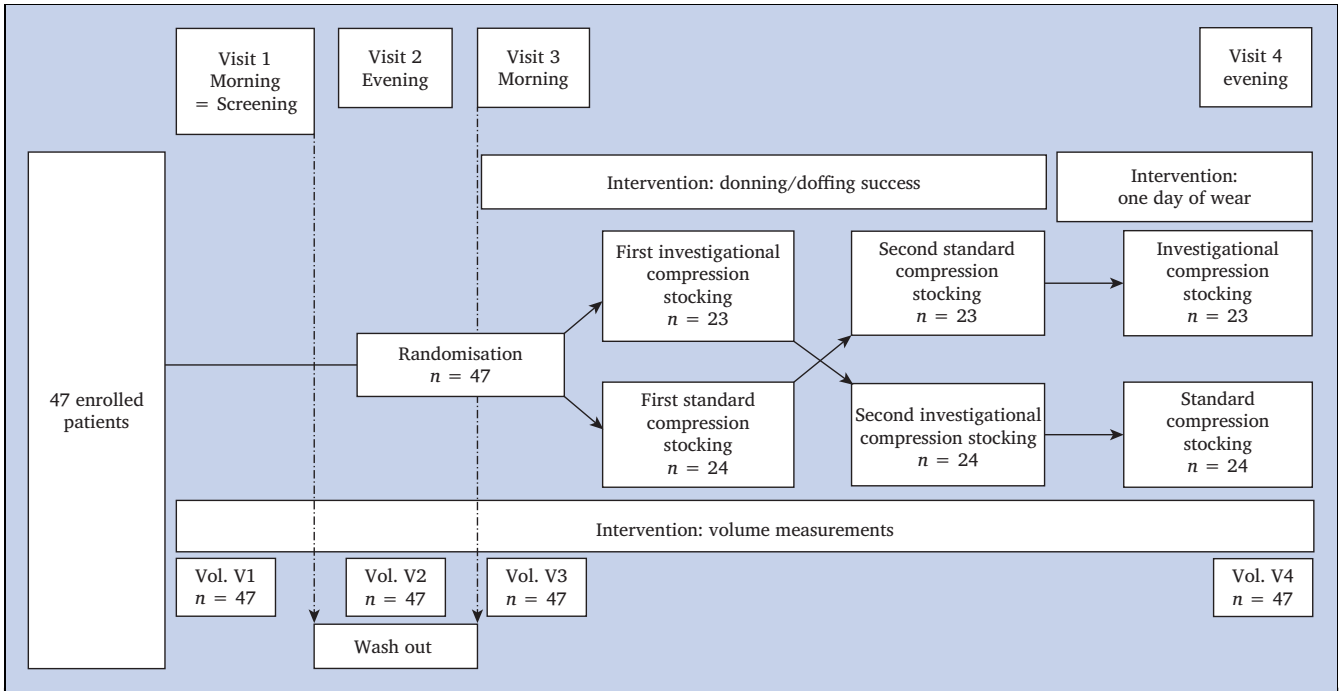


Figure 1. Timeline of the study visits for testing an investigational two layer stocking *vs.* standard stocking to compare the prevention of diurnal oedema in 47 participants suffering from chronic venous insufficiency. Visit 1 (V1; day 1 morning): morning volume measurement where patients wear their customary compression garment up to study entry. Measures were used to order an investigational and a standard trial stocking. Beginning of two day washout period without medical compression. Visit 2 (V2; day 2 evening): Evening volume measurement after a 1 day—1 night—1 day washout period without medical compression. Visit 3 (V3; day 3 morning): morning volume measurement after 1 day—1 night—1 day—1 night washout period without medical compression. Assessment of donning and doffing success with the investigational and standard compression stocking (open label randomised crossover trial). Subsequently, one day wear of randomly allocated compression stocking. Visit 4 (V4; day 3 evening): evening volume measurement where patients wore the randomly allocated investigational or standard stocking for at least 7 hours up to the moment of measurement. Assessment of the worn compression garment using the International Compression Club patient questionnaire.

were not required to have any prior experience of using compression stockings.

Exclusion criteria were known contraindications to compression therapy, for example peripheral arterial disease with an ankle brachial index of < 0.8 or > 1.3, suspected polyneuropathy with more than four insensitive test areas in the Semmes—Weinstein monofilament test, severe heart failure (New York Heart Association class III — IV), inability to reach the foot, allergy to the stocking material, and inability to follow the study procedures.[14] In each participant, only the more severely diseased leg was tested (Fig. 2).

The study was approved by the Ethics Committee of the Canton of Zurich and was conducted according to the Declaration of Helsinki principles. All study participants gave written informed consent and participated voluntarily. The trial was registered on ClinicalTrials.gov (NCT03429959).

Test stockings

Investigational compression stocking. The investigational device consists of two layers: a light understocking with closed toes exerting a pressure of 13 mmHg at the medial supramalleolar area, and an outer stocking with open toes exerting a pressure of 15 mmHg. The investigational two layer stocking exerted 27—29 mmHg pressure at the medial supramalleolar level but without compression in the foot and heel area. The investigated device complied with the manufacturing standards of the compression garment industry, has been CE certified, and is labelled accordingly. At the time of writing, the investigational stocking is not commercially available and has no brand name.

Standard compression stocking. The comparator stocking, SIGVARIS Cotton (SIGVARIS, St. Gallen, Switzerland), is a commonly prescribed standard, single layer compression stocking with closed toes exerting 23—32 mmHg substocking pressure at the medial supramalleolar area. The stocking has a CE mark and has been on the market for several years.

Interventions

Donning and doffing attempt. The stockings were prescribed according to the leg size measured in the morning visit (V1). After instruction by the clinical investigator, patients independently tried to don and doff the study stockings using only rubber gloves as aids. Each attempt was timed to provide a measure of donning and doffing ease.

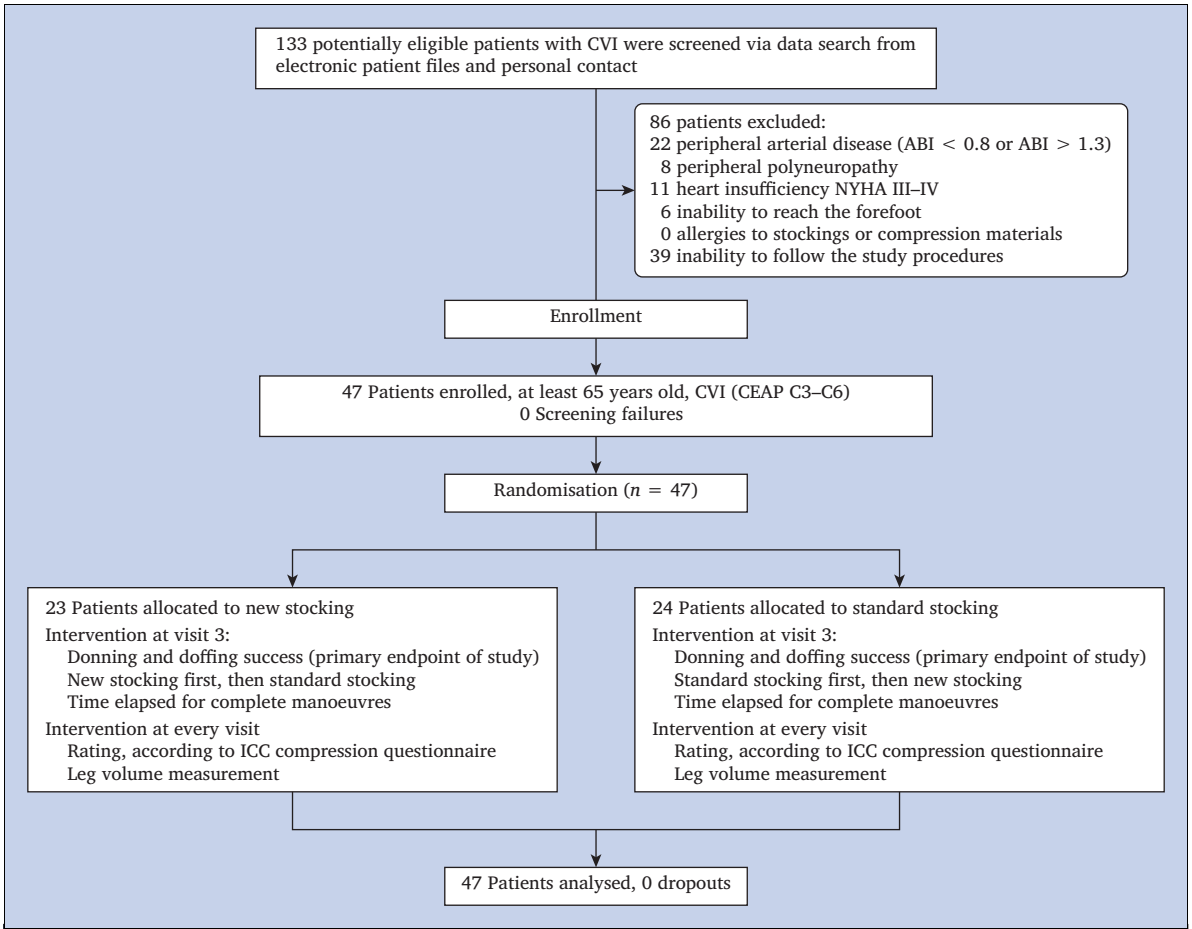


Figure 2. Consolidated Standards of Reporting Trials (CONSORT) flow diagram of study testing an investigational two layer stocking *vs.* standard stocking to compare diurnal oedema prevention with both types of stockings in an open label, randomised controlled setting in 47 participants suffering from CEAP class C3—C6 chronic venous insufficiency (CVI). ABI = ankle brachial index; NYHA = New York Heart Association; ICC = International Compression Club.

Evaluation of user friendliness. With the help of a shortened version of the International Compression Club (ICC) questionnaire, participants scored their donning and doffing attempts, as well as the immediate and sustained (after one day) comfort of wearing the stocking. The questionnaire was suggested by the ICC to compare observations in applicability of compression therapy. It included questions on the participant's normal compression therapy, as well as general and detailed questions assessing the effect and comfort of compression stockings (it can be downloaded at http://icc-compressionclub.com). The item *ease of donning and doffing* (to be filled in directly after the attempt) was selected, and the items pruritus, skin irritation, skin lesions, feeling of constraint, feeling of swelling, feeling of heat build up, feeling of pulsation, pain, leg cramps, garment sliding, leg strangulation, and local oedema (to be filled in after one day of wearing the randomly allocated trial stocking) were also chosen. All aspects were graded from 0 to 10, with 10 being the highest. One of the investigators (C.S.B.) read the questions aloud and patients gave their answers after each question was put to them.

Prevention of diurnal oedema. Leg volumes were measured using the truncated cone formula of Kuhnke (also called the disc model), measuring the leg circumferences at eight points at 4 cm intervals, starting at the smallest leg circumference up to the patella, and marked on the patient's leg to be reproduced at each visit. The method provides values that show good correlation with water displacement measurements ($r = 0.99$).[12,15] The measurements were taken at each of the four study visits (V1 — V4). Fig. 1 illustrates the timeline of volume measurements and donning/doffing attempts. V1 (in the morning, with customary compression garment) measurements were taken no later than two hours after the patient got out of bed. Measurements for V2 (in the evening, after a washout period of two days) and V3 (the following morning, no later than two hours after the patient got out of bed) were taken in the absence of medical compression. V4 (in the evening, after one day of compression with the investigational or the standard stocking, according to randomisation) was held at least seven hours after V3.

Randomisation

Each participant was allocated to one of two compression stocking test groups (investigational stocking or standard stocking) in a 1:1 ratio using a randomisation list. The list was generated by the statistician on a computer using a permuted block design with block sizes 2 and 4. To minimise bias through practice, the sequence in which the study stockings would be donned was defined for each study group. Participants first donned the allocated study group stocking, then the other stocking. Only the allocated study group stocking was further tested during a day of wear.

Statistics

A power analysis based on previous studies[8,11] showed that a sample size of 47 pairs would achieve 82% power to detect an odds ratio (OR) of 7.0 using a two sided McNemar test with a significance level of .05. The OR is equivalent to a difference between two paired proportions of 0.24, which occurs when the proportion in cell 1,2 (patient is able to don the investigational but not the standard compression stocking) is 0.28 and the proportion in cell 2,1 (patient is able to don the standard but not the investigational compression stocking) is 0.04. The proportion of discordant pairs is 0.32.

The exact McNemar test was used to compare donning and doffing success between the standard and the investigational compression stocking. A possible period effect was inspected by an exact McNemar test to compare the first and the second periods. For continuous variables and crossover data, the CROS estimator was used to compare the standard and investigational compression stocking, i.e., the difference between first and second period was calculated and compared between the randomisation groups with an exact Wilcoxon rank sum test. The CROS estimator has the advantage that it allows for control of the period effect. For all other variables (unpaired data), an exact Wilcoxon rank sum test was used to test the differences between the randomisation groups. For ordinal variables with very few categories (e.g. patient rating: pruritus and feeling of constraint), the Fisher's exact test was used.

All analyses were performed in the R programming language (version 3.6.2).[16] The "exact2x2" package[17] was used to compute the exact McNemar test, the "coin" package[18] was used to compute the exact Wilcoxon rank sum test. The "tableone" package[19] was used for descriptive statistics. All statistical tests and calculations were carried out by a biostatistician (N.T.G.).

RESULTS

Patient characteristics

The study demographics are listed in Table 1. The two study groups were comparable in terms of sex, distribution of CEAP clinical stage classification, and prior experience of compression therapy. The study group that was allocated to wear the investigational stocking for one day was significantly older (mean age 80.4 *vs.* 75.6 years; $p = .017$).

Donning and doffing success

All patients could don the investigational stocking ($n = 47$; 100%). By contrast, the success rate with the standard stocking was 75% ($n = 35$; $p < .001$). There was no significant period effect; the order in which the study stockings were donned (investigational stocking first or standard stocking first) was irrelevant. All patients were able to doff the investigational stocking ($n = 47$; 100%) *vs.* a 66% success rate with the standard stocking ($n = 31$; $p < .001$). There was also no period effect for doffing (Fig. 3).

Time to don and doff study stockings

For participants who were able to don both stockings ($n = 35$), the time taken to don the investigational stocking

Table 1. Characteristics of 47 patients aged ≥ 65 years with chronic venous insufficiency of CEAP class C3 − C6 studied for an investigational two layer stocking *vs.* a standard stocking to compare the prevention of diurnal oedema with both types of stockings in an open label, randomised controlled setting

Parameter	All participants (n = 47)	Investigational stocking (n = 23)	Standard stocking (n = 24)	p value
Male sex	24 (51)	12 (52)	12 (50)	.88
Age − y	78.0 ± 6.6	80.4 ± 6.9	75.6 ± 5.6	.017
BMI − kg/m^2	27.5 ± 4.4	27.5 ± 4.0	27.4 ± 4.8	.57
First time stocking user	33 (70)	15 (65)	18 (75)	.46
CEAP classification				.75*
C3	20 (43)	10 (43)	10 (42)	
C4 a/b	21 (45)	9 (39)	12 (50)	
C5	4 (8)	3 (13)	1 (4)	
C6	2 (4)	1 (4)	1 (4)	
Comorbidities				
Hypertension	27 (57)	12 (52)	15 (62)	.47
Diabetes	7 (15)	5 (22)	2 (8)	.25*
Dyslipoproteinaemia	14 (30)	7 (30)	7 (29)	.92
Smoker	1 (2)	1 (4)	0 (0)	.49*
Former smoker	12 (25)	6 (26)	6 (25)	.93
Heart failure − NYHA class I–II	2 (4)	2 (9)	0 (0)	.23*
CHD	6 (13)	5 (22)	1 (4)	.097*
AF and other cardiac disorders	14 (30)	7 (30)	7 (29)	.92
Respiratory disease	9 (19)	4 (17)	5 (21)	1.0*
Urogenital disease	13 (28)	7 (30)	6 (25)	.68
GI disease	9 (19)	4 (17)	5 (21)	1.0*
Dermatological disease	26 (55)	12 (52)	14 (58)	.67
Haematological disease	13 (28)	6 (26)	7 (29)	.81
Neurological disease	13 (28)	7 (30)	6 (25)	.68
Orthopaedic disease	22 (47)	14 (61)	8 (33)	.059
Rheumatic disorders	10 (21)	3 (13)	7 (29)	.29*
Any malignancy and no active treatment	6 (13)	4 (17)	2 (8)	.42*
Any allergies	2 (4)	0 (0)	2 (8)	.49*

Data are presented as n (%) or mean ± standard deviation. BMI = body mass index; NYHA = New York Heart Association; CHD = chronic heart disease; AF = atrial fibrillation; GI = gastrointestinal.
* Continuous variables (BMI and age) were compared with an exact Wilcoxon rank sum test. Categorical variables were compared with a chi square test or a Fisher exact test.

was significantly longer than for the standard stocking (median 146 seconds *vs.* 90 seconds; $p = .028$). It should be noted that the investigational stocking must be put on in two steps.

For the participants who were able to doff both stockings ($n = 31/47$), the time to doff was not significantly different between the two stockings (median time 33 seconds *vs.* 26 seconds; $p = .93$).

ICC patient questionnaire rating

The investigational stocking was rated significantly easier to don and doff than the standard stocking ($p < .001$ and $p < .001$, respectively). Participants assessed the particular items *vs.* the investigational stocking as follows: donning median 5.0 *vs.* 7.0 (mean 5.0 *vs* 7.2; $p < .001$); doffing median 5.5 *vs.* 10.0 (mean 4.9 *vs* 8.9; $p < .001$); pruritus median 0 *vs.* 0 (mean 0.2 *vs* 0.0; $p = .50$); skin irritation median 0 *vs.* 0 (p value not estimable); skin lesions median 0 *vs.* 0 (p value not estimable); feeling of constraint median 0 *vs.* 0 (mean 0.37 *vs* 0.04; $p = .24$); feeling of swelling 0 *vs.* 0 (mean 0.04 *vs* 0; $p = 1.0$); feeling of heat build up median 0 *vs.* 0 (p value not estimable); feeling of pulsation median 0 *vs.* 0 (p value not estimable); pain median 0 *vs.* 0 (mean 0.17 *vs.* 0.0; $p = .50$); leg cramps median 0 *vs.* 0 (p value not estimable); garment sliding median 0 *vs.* 0 (mean 0.75 *vs.* 0.35; $p = .48$); leg strangulation median 0 *vs.* 0 (mean 0.46 *vs* 0.30; $p = .69$); and local oedema 0 *vs.* 0 (mean 0.13 *vs.* 0; $p = 1.0$).

In terms of overall rating of wearing comfort, with respect to immediate comfort of wear after donning the stockings there was no statistically significant difference ($p = .072$). After seven hours of wear time, the investigational stocking was rated as statistically significantly more comfortable ($p = .036$).

Physical properties assessed by diurnal oedema prevention

Volume changes over time are given in Fig. 4(A, B). Diurnal oedema prevention can be measured by comparing V4 (after one day of trial compression stocking) to V2 (after one day without compression). Investigational and standard stockings prevent diurnal oedema to a comparable extent (−151 mL *vs.* −154 mL; $p = .79$) (Fig. 4C). Diurnal oedema prevention can also be measured by comparing V4 to V3

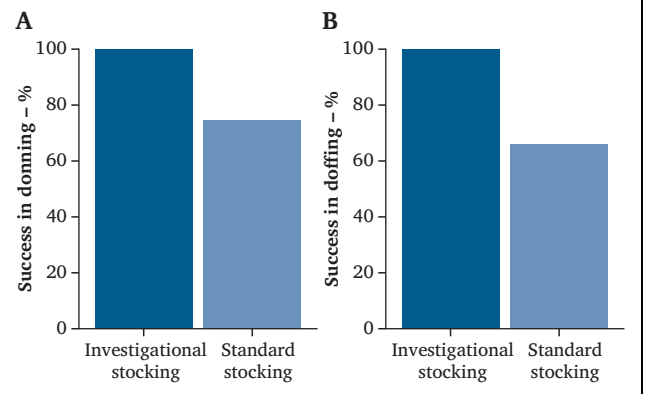


Figure 3. Success in (A) donning and (B) doffing of investigational ($n = 23$) and standard ($n = 24$) stocking favouring investigational stocking both in donning 100% *vs.* 74.5% ($p < .001$) and doffing 100% *vs.* 66% ($p < .001$).

(volume change over one day of wearing the trial stocking). Diurnal oedema prevention with the investigational and the standard stocking was comparably effective (−89 mL *vs.* −104 mL; $p = .47$) (Fig. 4D).

Foot oedema was neither reported by patients nor observed by investigators. Foot circumferences were not measured during this study.

DISCUSSION

Treatment compliance is a key issue in compression therapy, reaching approximately 60%, with a range of 20%—80%.[3—10] Difficulties with donning and doffing compression stockings are the principal reasons for non-adherence. Further complaints are poor comfort, with feelings of constraint, dryness, or skin irritation.[8—10]

If the foot is completely omitted, the narrow section at the ankle becomes easy to don. This has been shown previously.[11,20] However, the ankle end of the "leggings" tends to slide upwards,[11] and then the distal leg which is commonly most affected by chronic venous disease no longer receives sufficient compression. The investigational stocking overcomes this shortcoming as the compression free foot section holds the ankle section in place. Nevertheless, the investigational stocking remains significantly easier to don than a standard stocking with comparable substocking pressure.

The aim of this study was to demonstrate the superior ease of use and comfort of the investigational stocking while preserving the physical properties of a standard stocking.

In the studied patient population, the donning and doffing success of the investigational stocking was 100%, which was significantly better than the standard stocking (donning success 75%, doffing success 66%). To the authors' knowledge, this is the first compression stocking with a 100% success rate in unaided donning and doffing. The user friendliness of the investigational stocking was not only shown by the donning and doffing success, but also by the better ratings. The small disadvantage of a longer donning time for the investigational stocking *vs.* the standard stocking (median time 146 *vs.* 90 seconds; $p = .028$) had no impact on the overall subjective rating of the stocking. It was described as less strenuous to put on, and the time taken to doff both stockings was the same ($p = .93$).

The European Society for Vascular Surgery guidelines on the management of chronic venous disease discuss suboptimal patient compliance,[21] which is probably due to issues in putting on and removing elastic stockings, especially in the elderly. Moreover, lack of RCTs for both superficial venous incompetence and the post-thrombotic leg has resulted in uncertain evidence on the clinical effectiveness of elastic stockings. The investigational stocking may be relevant, as it helps to overcome suboptimal compliance. To fill the identified evidence gap, the clinical effectiveness of the investigational stocking should be demonstrated in future RCTs addressing the most common indications for compression therapy.

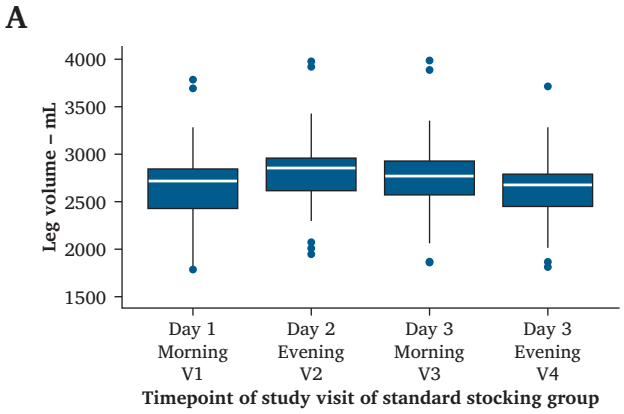
The ability to don and doff the stockings unaided will enhance patient independence and potentially reduce additional healthcare costs.[22,23]

One of the main effects of compression therapy is a reduction in oedema. Increased interface pressure of elastic compression stockings, especially at the gaiter area, negatively affects treatment compliance. Recent studies suggested that lower interface pressures might be sufficient.[3,24,25] However, especially in increased CEAP classes (> C4b), higher interface pressures at the gaiter area seem to have beneficial effects on the microcirculation.[26] The concept of relieving compression in the foot and heel area, while maintaining high pressures at the gaiter area, may open a new avenue in applying a sufficiently strong interface pressure, while maintaining high treatment comfort and adherence.

In this study, there was no significant difference in the diurnal leg volume changes between the two stockings. Both study stockings limited diurnal leg swelling, and even slightly decreased leg volumes over one day of wear (investigational stocking −89 mL *vs.* standard stocking −104 mL; $p = .47$). Lack of foot and heel compression does not compromise clinical effectiveness. Importantly, compensatory foot oedema was not an issue in the investigational stocking study group, although this remains to be corroborated by measurements in future studies. For comparison, foot sparing post-operative bandages also cause no foot swelling.[20]

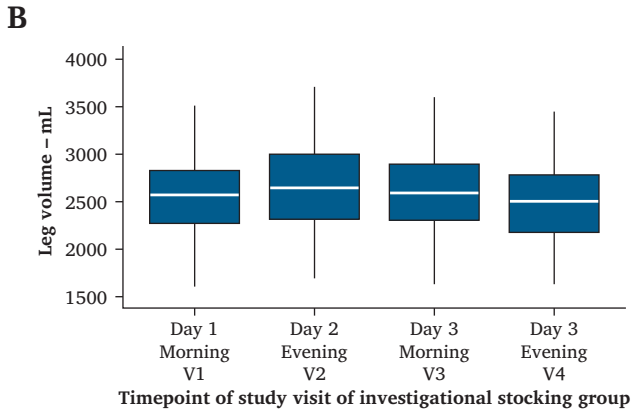
Limitations

Bias due to the open label design of this RCT cannot be excluded. It was impossible to blind patients or clinical investigators to the investigational device as it consists of two overlapping garments, whereas the standard stocking is a single layer. The crossover design could have been extended to the one day wear test if all patients had worn each study stocking for a whole day. Physical activities and medication may have influenced leg volumes. One day of wear comfort



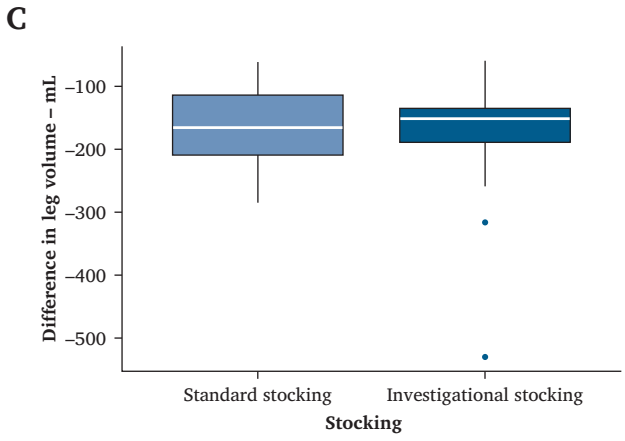
Maximum	3791 mL	3969 mL	3983 mL	3707 mL
3rd quartile	2841 mL	2956 mL	2920 mL	2789 mL
Median	2719 mL	2852 mL	2766 mL	2670 mL
1st quartile	2419 mL	2608 mL	2565 mL	2449 mL
Minimum	1786 mL	1945 mL	1861 mL	1814 mL

V4 – V2: –151 (–210 – –115) mL
V4 – V3: –104 (–165 – –71) mL
V2 – V1: +155 (+55 – +199) mL
V3 – V1: +74 (+29 ml – +177) mL



Maximum	3503 mL	3706 mL	3598 mL	3446 mL
3rd quartile	2825 mL	3000 mL	2896 mL	2775 mL
Median	2573 mL	2643 mL	2584 mL	2499 mL
1st quartile	2267 mL	2314 mL	2305 mL	2172 mL
Minimum	1596 mL	1686 mL	1635 mL	1626 mL

V4 – V2: –154 (–189 – –136) mL
V4 – V3: –89 (–137 – –62) mL
V2 – V1: +82 (+41 – +132) mL
V3 – V1: +32 (+2 – +66) mL



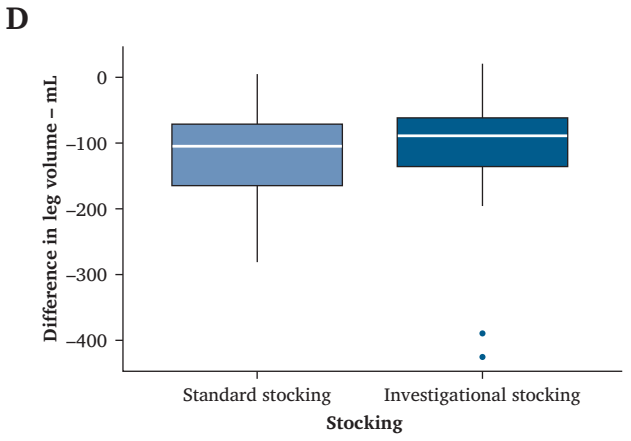


Figure 4. Leg volumes in patients allocated to (A) standard compression stocking (n = 24) or (B) investigational compression stocking (n = 23) at different time points: V1–V4 (see Fig. 1) and the volume differences displayed as median with interquartile ranges in V4–V2 (evening oedema with trial compression stocking *vs.* evening oedema without compression), V4–V3 (diurnal oedema using trial stocking), V2–V1 (diurnal oedema without compression), and V3–V1 (morning oedema without compression stocking compared with morning oedema, accustomed compression). (C) Diurnal oedema prevention comparing V4–V2, where the volume difference for standard stocking was −151 mL (−210 mL – −115 mL) *vs.* investigational stocking: −154 mL (−189 mL – −136 mL; p = .79). (D) Diurnal oedema prevention through one day of wear time V4–V3, where the volume difference for standard stocking was −104 mL (−165 mL – −71 mL) *vs.* investigational stocking: −89 mL (−137 mL – −62 mL; p = .47).

is a short time to assess the comfort of a device designed for the treatment of a chronic disease. Foot volume measurements would have been useful to quantify the casual observation that foot swelling was neither reported by patients nor observed by investigators. The physical properties of the pressure profile (multisite substocking pressure measurements), the static stiffness index, and the venous ejection fraction of the investigational stocking will follow in a separate study.

Conclusions

The investigational stocking, which has no compression in the foot and heel area, was significantly easier to don and doff, while displaying no inferior oedema prevention properties, compared with a standard stocking of the same compression class. The next step will be to prove the physical properties, particularly diurnal foot volume changes and clinical effectiveness, in further RCTs.

CONFLICTS OF INTEREST

In the event of the commercialisation of the investigational stocking, none of the authors or co-authors shall privately profit. Julia Fleischer and Reinhard Kluge are textile engineers and employees of SIGVARIS AG, Switzerland. SIGVARIS AG and the principal investigator, Jürg Hafner, have agreed that, in the event of market introduction, SIGVARIS AG will donate 2% of the selling price towards research. Two thirds of that sum (1.33% of the profit) will be transferred to the JH Rahn Foundation, Zurich, which is dedicated to research and teaching in phlebology and dermatological surgery, and one third (0.67%) will be transferred to the University of Zurich.

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APPENDIX A. SUPPLEMENTARY DATA

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ejvs.2020.09.027.

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