

ORIGINAL ARTICLE

An investigation of the ability to produce a defined 'target pressure' using the PressCise compression bandage

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Abstract

Compression therapy is the cornerstone in the prevention and treatment of leg ulcers related to chronic venous insufficiency. The application of optimal high pressure is essential for a successful outcome, but the literature has reported difficulty applying the intended pressure, even among highly skilled nurses. The PressCise bandage has a novel design, with both longitudinal and horizontal reference points for correct application. In the current experimental study, the results for the general linear model, where the data set is treated optimally, showed that all 95% confidence intervals of the expected values for pressure were, at most, 5 mmHg from the target value of 50 mmHg, independent of the position on the leg and the state of activity. Moreover, even nurses with limited experience were consistently able to reach the targeted pressure goal. Future studies are needed to determine how well the bandage works on legs of different shapes, the optimal way of using the bandage (day only or both day and night) and whether the bandage should be combined with an outer bandage layer. In addition, special attention should be paid to subjective patient experiences in relation to the treatment as pain, discomfort and bulk are factors that can compromise patients' willingness to adhere to the treatment protocol and thereby prolong the healing process.

Introduction

Chronic venous insufficiency (CVI) has a wide spectrum of manifestations of which more severe symptoms, such as skin changes and ulcer formation, cause considerable morbidity, diminished quality of life and high treatment costs (1,2). For example, Drew *et al.* (3) estimated that, in Hull and East Yorkshire alone, GBP 9.29 million was spent on venous leg ulcer care from 2005 to 2006. The prevalence of CVI has shown to be about 7–8% (4,5), and it is estimated that approximately 20% of those with CVI develop venous ulcers. Compression therapy is the cornerstone in the prevention and treatment of CVI-related symptoms (6). The literature clearly shows that compression is more effective than no compression and also that high compression is more effective than low compression (7,8). Moreover, adherence to high levels of compression after healing reduces the rate of recurrence (8).

It is also known that the effect and efficacy of compression are highly dependent on the applied sub-bandage pressure and that this depends on the individual applying the bandage (9). The correct application of the sub bandage is of particular importance when it is used to promote wound healing (10).

Key Messages

- high compression therapy is effective in preventing and treating venous leg ulcers; thus, insufficient compression therapy can delay wound healing and prolong patient suffering
- a major problem is that the compression obtained is highly dependent on the individual applier, and studies have shown that the variance in sub-pressure is high even among highly experienced and skilled nurses

- this current study investigated a new compression bandage's ability to provide strong pressure (40–60 mmHg) irrespective of the leg radius and the applier, provided that the applier follows the visual guide of the bandage
- the study found that the PressCise bandage produced a precise and constant pressure homogeneously over the leg and the states, and even nurses with limited experience were consistently able to reach the targeted pressure goal
- future studies are needed to determine how the PressCise bandages can be best used for various conditions and how well the bandage is tolerated by the patients

At the present time, different classification systems are used in the USA, UK, France and Germany. A common international compression standard is lacking, but guidelines were established by members of the International Compression Club (ICC) (11), where a classification system was defined for the clinical studies of compression devices for venous disorders of the lower limbs. According to these guidelines, sub-bandage pressure of <20 mmHg is categorised as *mild*, 20–40 mmHg as *medium*, 40–60 mmHg as *strong* and ≥ 60 mmHg as *very strong*.

Although a common pressure standard might have been agreed upon, the main problem remains; the compression obtained is highly dependent on the individual applying the bandages (11). Reynolds (12) measured the impact of a training programme on nurses' bandaging skills to establish whether any improvements are maintained over time. The conclusion was that, even though the nurses receive accurate training in applying a compression bandage that helps them improve the sub-bandage pressure during a period of time (6–10 weeks), the maintenance of these skills over time is limited, and the nurses tend to fall back into their original routine. The study also shows that the specified aim of a 50% overlap for each turn of the bandage was not achieved or maintained over time.

In a study by Keller *et al.* (9), a bandaging training programme using pressure sensors was evaluated. The study shows that, despite careful training, the variation in sub-bandage pressure is high. All the 21 participating nurses were working at a dermatology clinic where compression bandage treatment was part of their daily work. Every nurse applied three consecutive compression bandages on a healthy volunteer. Measurements were made in supine and standing positions, both before and after the training programme. In the study, it was shown that only 57% of the bandages were applied with the target pressure of 20–40 mmHg, categorised as *medium*, in the supine position, both before and after the training programme. It was also shown that both the mean of and the variation in the applied sub-bandage pressures were greater after the training. The nurses were also asked to fill out a self-rating questionnaire on how confident they were about applying adequate pressure. The mean of that evaluation was 3.72 before the training and 3.29 after the training, on a scale from 1 (very confident) to 10 (unconfident). Thus, even among the most experienced and skilled bandage appliers, creating well-defined sub-bandage pressure is a challenge. There are currently a number of products in the market that use visual guides to

monitor the stretching force applied. These visual guides include rectangles (or ellipses) that become squares (or circles) at a specific elongation. However, controlling the stretching force and the amount of bandage overlap is not enough as applying a constant stretching force and overlap for various leg radii produces different pressures, according to Laplace's law where a small leg radius presents a higher sub-bandage pressure. Recently, a new compression bandage (PressCise, PressCise AB, Sweden) has been developed, and it is claimed that this new bandage provides a predefined pressure, irrespective of leg radius and irrespective of who applies it, provided that the person applying it follows the visual guide for the bandage. This study aims to evaluate this bandage by addressing the following questions:

- Question 1: Is the expected pressure within the guidelines (11) for strong sub-bandage pressure, i.e. 40–60 mmHg, achieved when different nurses apply the bandage?
- Question 2: Is the pressure homogeneous over the leg?
- Question 3: Is the pressure homogeneous over the states (i.e. supine, standing, after work)?

Materials and methods

Study design

This study has an experimental, descriptive, comparative design with within- and between-subject comparisons.

Participants

A consecutive sampling method was used. Information about the study was published at two universities and two hospitals, and the first 21 eligible nurses were included in the study. The sample size of 21 was used for comparability with a previous study by Keller *et al.* (9). The participating nurses' working experience, ranged from 1 to 43 years. The nurses worked within a variety of different departments, such as the dermatology clinic, home care, elderly care, psychiatry, infection, medicine, vascular surgery, thoracic surgery, sports medicine, anaesthesia, pre-hospital, geriatrics, stroke clinic, rehab care and intensive care. Six of the nurses never applied bandages, 12 nurses applied bandages 1–4 times a month and 3 of them 30–40 times a month. None of the nurses had used the PressCise bandage prior to the study. The study was performed in accordance with the ethical principles outlined in the Declaration of Helsinki and is consistent with good clinical practice (GCP). The study was also approved by the ethics committee in Gothenburg (Dnr 5.1-2013-103889) and the Medical Products Agency in Sweden prior to the start of the study. The healthy volunteer signed a written informed consent prior to the start of the study.

The bandage

The device used in this study was the new PressCise compression bandage (PressCise AB). The aim of the PressCise bandage is to provide a comprehensible guide to the person applying the bandage in order to obtain a predefined pressure, which, in this

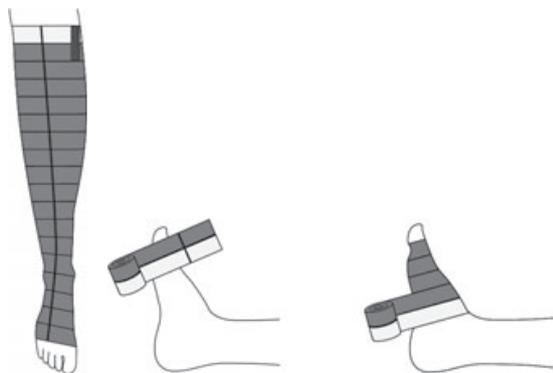


Figure 1 An illustration of how the PressCise bandage is applied. Note that the overlap is controlled by the longitudinal marking and the tension by aligning the shorter lines. This means that the same amount of textile is used for every turn, independent of the leg radius. As a result, a higher stretching force is needed on the thicker parts of the leg, compensating for the greater radius, according to Laplace's law, in order to obtain constant pressure. (Copyright: PressCise AB)

study, was 50 mmHg. The bandage has a longitudinal marking to make the overlap constant. Perpendicular to this longitudinal marking are markings that are a consistent distance apart in order to be aligned for each bandage turn (see Figure 1). As a result, a higher stretching force is applied to thicker parts of the limb, but at the same time the curvature of the limb is less in the thicker part. Given the specific elastic property of the bandage material, these two features – higher tension and less curvature – compensate for one another, according to Laplace's law, resulting (in theory) in a constant sub-bandage pressure.

Procedure

Two pressure sensors were placed on the leg of a healthy female volunteer at the recommended places for sub-bandage pressure monitoring (11) – at the positions called B1 and C. The B1 position is approximately 10–15 cm proximal to the medial malleolus where the Achilles tendon changes into the calf muscles, while the C position is where the calf is at its maximum girth. The pressure measurement device that was used was PicoPress by Microlab Italia, a sensor that is thin and flexible (11). A previous study (13) and our own tests showed that PicoPress® was the most reliable device currently on the market. The average variation coefficient for the PicoPress has been shown to be 2.79% (13). The device is digital and calibrates itself automatically at start-up. Each nurse carried out one test application before the actual measurements were made. Measurements of sub-bandage pressure on the leg of the volunteer were made for supine, standing and after work, that is after six tip-toes. Three consistent bandage applications and measurements were performed after the first test application.

Statistics

The study was partly designed to enable comparisons with the study by Keller *et al.* (9). However, our design also gives us the opportunity to answer the questions posed at the end of the Introduction section. To answer these research questions, we

studied the data in several ways. In Question 1, the data was split by position and state. Each individual measurement as well as their average (per nurse)[†] were analysed. In Question 2, the data were split by state. For each bandaging, the measurements in the two positions (B1 and C) constitute a paired replicate for each nurse. By computing the difference, these dependencies in the data were taken into account. The response variable was therefore the difference in pressure between the ankle (position B1) and the calf (position C). This was done for the single measurements as well as the mean value of the differences (per nurse). In Question 3, the data were split by position. The response variable was the difference in the pressure taken between pairs of states. Again, each difference was computed for each nurse as there was a paired design with dependencies similar to the responses in Question 2. In this case, only the mean values of the three measurements were used and not every single repetition.

The aim of the single measurements was to show the closeness of the readings to the target value of 50 mmHg. When making comparisons between the positions and between the states, the aim was to show the closeness of the readings to zero. For this reason, hypothesis testing is not useful as hypotheses are supposed to be rejected. Instead, we chose to use confidence intervals (CIs) for the appropriate expected values.

First, simple statistical methods were used where the data were split with respect to the objective according to the questions posed above. In each case, one-sample CIs using *t*-distribution were calculated. Based on the single measurements and on the means, we made comparisons with target values and the categorising intervals for them (11). For the pressure on specific positions on the leg, the CIs were compared with the value of 50 ± 10 (following the guidelines for the category of *strong*). For the comparisons of the positions over the leg and pair-wise over the states, the expected differences should be as close to zero as possible.[†] Model checks on the residuals showed that the normal distribution was a suitable model. This applied both to the single measurements and to the difference over the legs and over the states.

One drawback of these initial approaches, where each question required different ways of dealing with the data and with dependencies, was that the sample size was $n = 21$. The split of the data set given above was made so that comparisons with other studies in this area could be made. However, this did not give us the opportunity to elucidate the entire situation. A more holistic approach was therefore adopted and a richer model was applied, where we used all the data at the same time and in a more effective way. This model was one in which the pressure is described by the fixed factors, *position* and *state*, as well as their *interaction*, but we also had to model the dependencies in the data. This was done by adding the factor term *nurse* as a random effect. Together with the traditional *error* term, these two contribute to the variances and covariances in the model. Further, in this model, no abnormalities were detected. This general linear model with the assumption of normal distribution, therefore, provided a good fit for the data.

As this was a pilot study, no correction for multiple testing was made, and the 95% confidence level was applied in all

[†]Correction added on 19 November 2015, after first online publication: superfluous text added during production has been deleted.

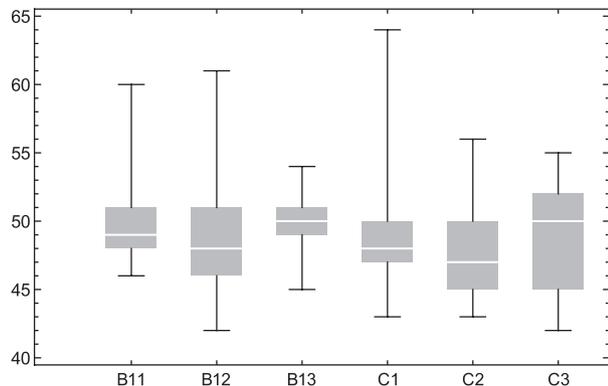


Figure 2 Box plots for the pressure (mmHg) in the resting state at positions B1 and C, with the last index representing application numbers 1, 2 and 3 ($n=21$); for example, B12 represents the second application at position B1

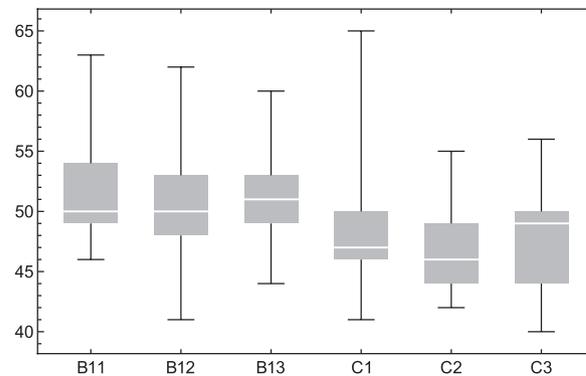


Figure 4 Box plots for the pressure (mmHg) in the after-work state at positions B1 and C in application numbers 1, 2 and 3 ($n=21$)

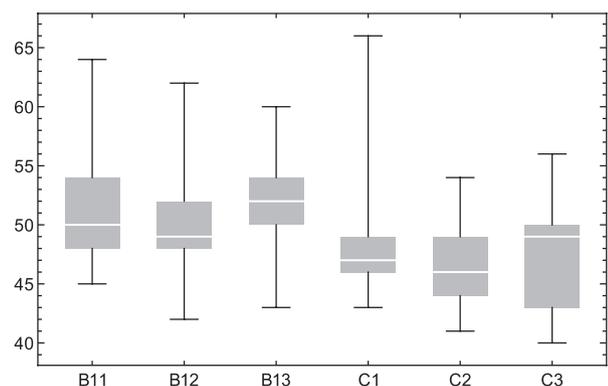


Figure 3 Box plots for the pressure (mmHg) in the standing state at positions B1 and C in application numbers 1, 2 and 3 ($n=21$)

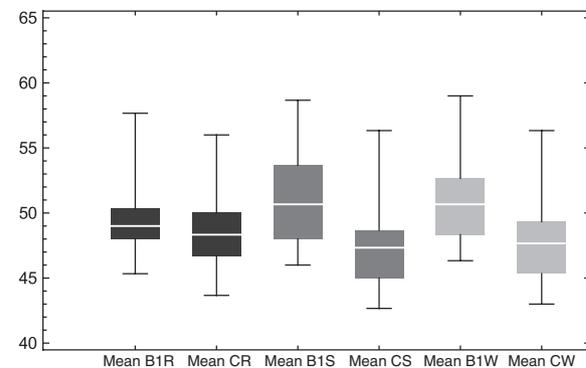


Figure 5 Box plots for the mean values of the pressure (mmHg) in positions B1 and C for the states of resting (R), standing (S) and after work (W) ($n=21$)

the cases.[†] The output for this paper was generated using SAS software, Version 9.2 for Windows. Copyright (c) 2014 SAS Institute Inc, Cary, NC, USA.

Results

The results for Question 1 are presented or summarised for all the cases, that is, both for the individual variables and for

[†]Correction added on 19 November 2015, after first online publication: superfluous text added during production has been deleted.

their mean. For Questions 2 and 3, we only present the results for the mean values. First, we illustrate each measurement of the pressure for the different states and positions in box plots (Figures 2–4) and for the mean values (Figure 5). In all the cases, the y-axis represents the measurements in mmHg.

The results of the statistical analysis of the single measurements split by position and state (Question 1) show that all 95% CIs of the expected values for pressure were at most 6 mmHg from the target value of 50 mmHg. For the separate states, we have a maximum of 4 mmHg, 6 mmHg and 5 mmHg from 50 mmHg for resting, standing and after work states, respectively. However, this is only a very rough description with rounded values of the worst cases for the real results.

The exact results can be found in detail in Table 1.

Table 1 95% Confidence intervals for each application, numbers 1, 2 and 3

Resting ($n=21$)				Standing ($n=21$)				After work ($n=21$)			
Variable	Mean	SEM	95% CI	Variable	Mean	SEM	95% CI	Variable	Mean	SEM	95% CI
B11	50.5	0.81	(48.8; 52.2)	B11	51.4	1.06	(49.2; 53.6)	B11	51.9	0.99	(49.8; 53.9)
B12	48.5	0.89	(46.6; 50.3)	B12	49.9	1.01	(47.8; 52.1)	B12	50.0	1.00	(48.0; 52.1)
B13	49.4	0.60	(48.2; 50.7)	B13	51.2	0.99	(49.2; 53.3)	B13	51.2	0.94	(49.2; 53.1)
C1	48.8	0.89	(46.9; 50.6)	C1	48.1	1.05	(45.9; 50.3)	C1	48.1	1.02	(46.0; 50.3)
C2	47.9	0.79	(46.3; 49.5)	C2	46.3	0.77	(44.7; 47.9)	C2	46.8	0.77	(45.2; 48.4)
C3	48.8	0.80	(47.1; 50.4)	C3	47.6	0.96	(45.6; 49.6)	C3	48.0	0.93	(46.1; 49.9)

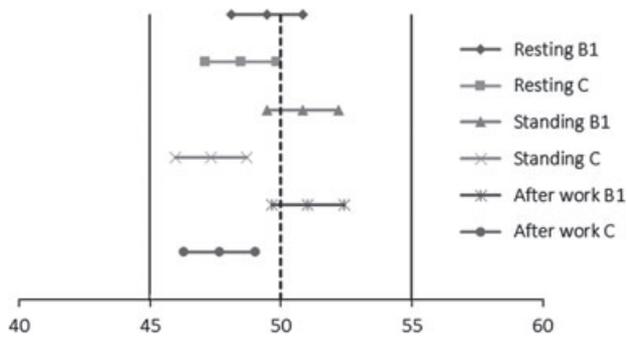


Figure 6 95% Confidence intervals of the pressure (mm Hg) for the different combinations of state and position; the vertical dashed line is the target value, and the solid lines indicate the optimal pressure interval

In what follows, we only present the compressed forms of the results. The Appendix gives the exact values of all the CIs.

Calculations based on the mean of the repetitions split by position and state gave CIs that were at most 5 mmHg from 50 mmHg. According to the guidelines for categorising the sub-bandage pressure as strong (11), we achieved this in all the cases both for the separate repetitions and for the mean values.

Next, we studied the homogeneity over the leg and over the states. The results for the differences in positions on the leg (Question 2), with calculations based on the mean values of the repetitions, gave CIs that were at most 3 mmHg from 0 for resting, 6 mmHg from 0 for standing and 6 mmHg from 0 for the ‘after work’ state. The results for the pair-wise mean differences over the states (Question 3) revealed that all CIs were at most

3 mmHg from 0 for the B1 position and 2 mmHg from 0 for the calf. We leave the comparisons to those individuals who are able to judge the significance of the subject matter as there are no known guidelines for homogeneity.

The results from the general linear model, the details of which are given in the Appendix, were based on treating all the data at the same time. This gave us better precision and power than the cases in which the data were split into subgroups. In a model of this kind, we also had the opportunity to study how the factors (*position* and *state*) interacted. In the study of the main factors, we were able to see that the CIs for the positions and for the states were all less than 4 mmHg from 50 mmHg. The pair-wise differences in the states were all at most 2 mmHg from 0, and the difference in the position was less than 4 mmHg from 0.

When we studied the details from the *interaction* term, which was significant, the CIs were all at most 5 mmHg from 50 mmHg for each combination of state and position (see Figure 6). For all the relevant pair-wise differences, the CIs were all at most 5 mmHg from 0.

We also checked the stability of the measurements over the three repetitions by illustrations of the standard deviations for each nurse (Figures 7–9). All the nurses but one had a standard deviation of < 5 mmHg.

Discussion

This study aimed to evaluate the PressCise bandage by addressing three main questions. The first question was whether the expected pressure for a strong sub-bandage, that is a pressure between 40 and 60 mmHg, could be achieved when different

Figure 7 The standard deviation (on the y-axis) for the measurement in the resting state for nurse no. 1, ..., 21 (on the x-axis)

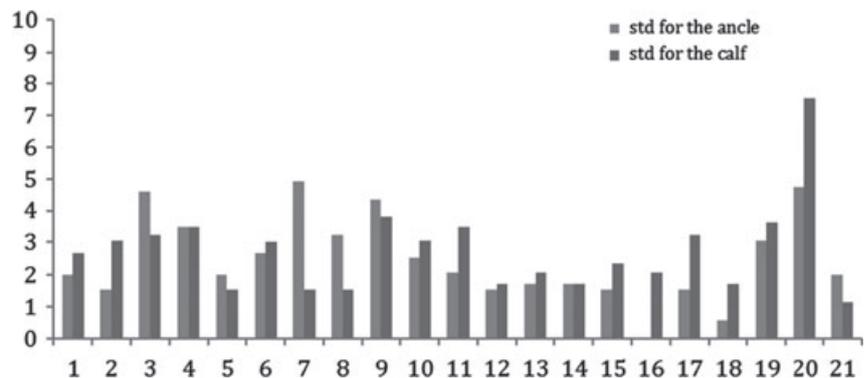
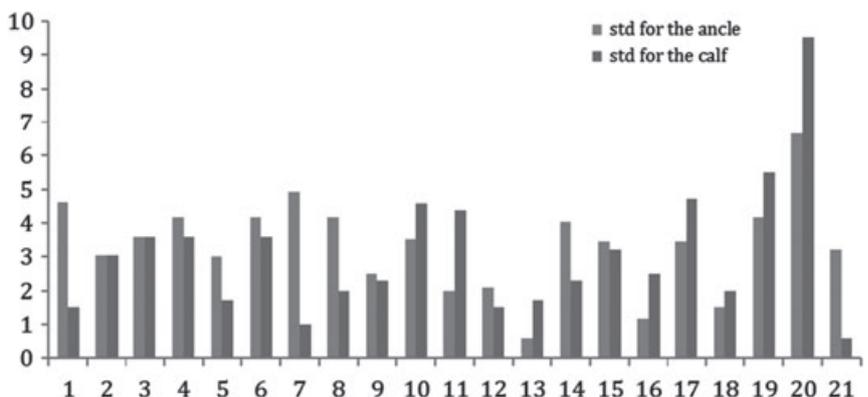


Figure 8 The standard deviation for the measurement in the standing state for nurse no. 1, ..., 21



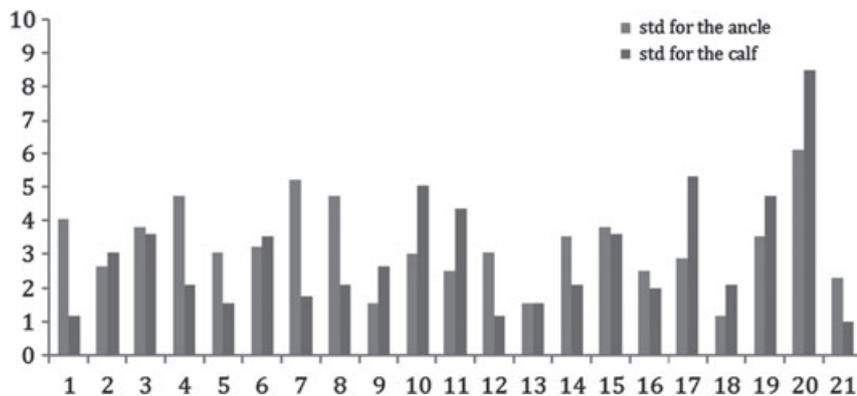


Figure 9 The standard deviation for the measurement in the after work state for nurse no. 1, ..., 21

nurses apply the bandage. This was shown to be the case. In fact, the results for the general linear model, where the data is treated optimally, showed that all 95% CIs of the expected values for pressure were at most 5 mmHg from the target value of 50 mmHg, independent of the person applying the bandage, the position on the leg and the state of activity. This is an important finding as constant strong pressure creates optimal healing conditions (7,11). The other two questions – whether the pressure was homogeneous over the leg and over the states – were also confirmed. The pressure was shown to be similar between the two different leg positions, B1 and C, and the pressure was homogeneous for the three different states of activity: resting, standing and after work. The results for the PressCise bandage must therefore be regarded as promising.

In this study, the sub bandage that was used was developed to achieve a target pressure of 50 mmHg, which, according to guidelines, is a pressure within the compression category of *strong*. In the study by Keller *et al.* (9), pressure between 35 and 45 mmHg was rated as optimal to achieve sufficient and safe compression. However, only 32% of the nurses who participated in their study applied a pressure within this range after training, although most of the nurses were highly skilled in compression bandaging. In contrast, in the current study, we found that even nurses with limited experience of compression treatment were consistently able to reach the targeted pressure goal by using PressCise.

This study was designed to enable comparisons with other studies of bandage pressure and the set-up was therefore partly the same as that in the study by Keller *et al.* (9), with three applications for each nurse. The sample size was 21, which was the number of nurses, in the simple statistical methods. The measurements made by the same person had to be handled carefully to avoid treating the total set of data as independent. However, some extensions of Keller's original set-up was chosen in the present study; both the position on the leg and different activities were incorporated. This enabled us to examine the stability properties of the pressure.

Conclusion

Even nurses with limited experience of compression treatment were consistently able to reach the targeted pressure goal by using the PressCise bandage. We also found that the mean pressure did not differ depending on the test subject's activity state and position on the leg, indicating that the bandage is able

to maintain near-constant pressure. Further studies are needed to determine how the PressCise bandage can best be used in the treatment of CVI-related symptoms.

Implications for clinical practice and further research

Although the results for the PressCise bandage are promising, further studies are needed. The PressCise bandage is a highly elastic bandage, and the high pressure of 50 mmHg might not be well tolerated by the patient, especially during bed rest (14). First of all, simple comparisons are needed of bandages with different targets but also of applying bandages on different patients. Moreover, the optimal way of using the bandage (day only or both day and night) has to be evaluated through longitudinal studies to investigate the properties for such a highly elastic bandage as the PressCise. Furthermore, it is generally accepted that mobile patients benefit from a low resting pressure and a high working pressure (14). To achieve this, a PressCise bandage with a lower target pressure, combined with an outer stiffer bandage layer, might be a good combination for mobile patients and patients with arterial insufficiency. In addition, special attention should be paid to subjective patient experiences in relation to the treatment as pain, discomfort and bulk are factors that can compromise patients' willingness to adhere to the treatment protocol and thereby prolong the healing process (8,15,16).

Acknowledgements

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Appendix

Table A1 95% Confidence intervals for the mean values

Resting (n=21)			Standing (n=21)			After work (n=21)		
Variable	Mean	95% CI	Variable	Mean	95% CI	Variable	Mean	95% CI
B1	49.460	(48.186; 50.735)	B1	50.841	(49.192; 52.491)	B1	51.032	(49.457; 52.606)
C	48.476	(47.189; 49.763)	C	47.317	(45.897; 48.738)	C	47.651	(46.248; 49.053)

Results for the mean values for each nurse by position and state

Table A2 95% Confidence intervals for the difference between positions for each application, numbers 1, 2 and 3

Resting (n=21)			Standing (n=21)			After work (n=21)		
Difference	Mean	95% CI	Difference	Mean	95% CI	Difference	Mean	95% CI
B11–C1	1.714	(–0.002; 3.430)	B11–C1	3.286	(1.296; 5.276)	B11–C1	3.714	(1.876; 5.553)
B12–C2	0.57	(–2.05; 3.19)	B12–C2	3.67	(0.94; 6.39)	B12–C2	3.24	(0.66; 5.82)
B13–C3	0.67	(–1.49; 2.83)	B13–C3	3.62	(0.54; 6.70)	B13–C3	3.19	(0.44; 5.94)

The difference calculated per nurse between ankle and calf on each single measurement (the three repetitions as an index at B1 and C)

Table A3 95% Confidence intervals of the mean values for the difference between the positions

Difference	Mean difference	95% CI
B1 – C for resting	0.98	(–0.65; 2.62)
B1 – C for standing	3.52	(1.60; 5.44)
B1 – C for after work	3.38	(1.65; 5.11)

The difference calculated per nurse between ankle and calf; the sample size is $n=21$ in each case

Table A4 95% Confidence intervals of the mean values for the difference between the states

Position B1 (n=21)			Position C (n=21)		
Difference	Mean difference	95% CI	Difference	Mean difference	95% CI
Resting – standing	–1.38	(–2.20; –0.56)	Resting – standing	1.16	(0.70; 1.62)
Resting – after work	–1.57	(–2.30; –0.84)	Resting – working	0.83	(0.35; 1.30)
Standing – after work	–0.19	(–0.59; 0.21)	Standing – working	–0.33	(–0.48; –0.19)

The difference calculated per nurse between pairs of states; the sample size is $n=21$ in each case

Table A5 Results from the larger model including both state and position and their interactions as fixed factors and 'nurse' as a random factor; output from SAS

Covariance parameter estimates	
Covariance parameter	Estimate
Nurse	5.2188
Residual	4.8081

Type 3 tests of fixed effects				
Effect	NDF	DDF	F Value	Pr > F
State	2	100	0.32	0.7266
Position	1	100	45.30	<0.0001
State * position	2	100	4.45	0.0141

Least squares means, <i>df</i> = 100, confidence level = 0.95						
Effect	State	Position	Estimate	SEM	Lower	Upper
State	Resting		48.9683	0.6025	47.7729	50.1636
State	Standing		49.0794	0.6025	47.8840	50.2747
State	Working		49.3413	0.6025	48.1459	50.5366
Position		B1	50.4444	0.5699	49.3137	51.5752
Position		C	47.8148	0.5699	46.6841	48.9456
State * position	Resting	B1	49.4603	0.6910	48.0894	50.8312
State * position	Resting	C	48.4762	0.6910	47.1053	49.8471
State * position	Standing	B1	50.8413	0.6910	49.4704	52.2122
State * position	Standing	C	47.3175	0.6910	45.9466	48.6884
State * position	Working	B1	51.0317	0.6910	49.6608	52.4027
State * position	Working	C	47.6508	0.6910	46.2799	49.0217

Differences of least squares means, <i>df</i> = 100, confidence level = 0.95								
Effect	State	Position	State	Position	Estimate	SEM	Lower	Upper
State	Resting		Standing		-0.1111	0.4785	-1.0604	0.8382
State	Resting		Working		-0.3730	0.4785	-1.3223	0.5763
State	Standing		Working		-0.2619	0.4785	-1.2112	0.6874
Position		B1		C	2.6296	0.3907	1.8545	3.4047
State * position	Resting	B1	Resting	C	0.9841	0.6767	-0.3584	2.3267
State * position	Standing	B1	Standing	C	3.5238	0.6767	2.1813	4.8663
State * position	Working	B1	Working	C	3.3810	0.6767	2.0384	4.7235
State * position	Resting	B1	Standing	B1	-1.3810	0.6767	-2.7235	-0.03841
State * position	Resting	B1	Working	B1	-1.5714	0.6767	-2.9140	-0.2289
State * position	Standing	B1	Working	B1	-0.1905	0.6767	-1.5330	1.1521
State * position	Resting	C	Standing	C	1.1587	0.6767	-0.1838	2.5013
State * position	Resting	C	Working	C	0.8254	0.6767	0.5171	2.1679
State * position	Standing	C	Working	C	-0.3333	0.6767	-1.6759	1.0092

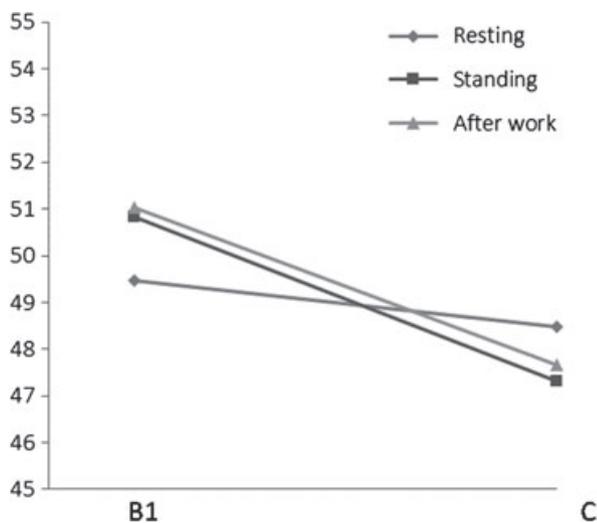


Figure A1 An interaction plot of position (on the x-axis) and state (the separate lines) with mmHg on the y-axis.