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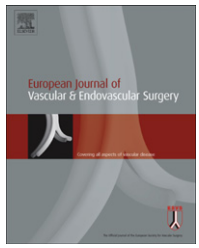

Ease of Application of Medical Compression-stocking Systems for the Treatment of Venous Ulcers

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Abstract *Objective:* To evaluate the ease of application of two-piece, graduated, compression systems for the treatment of venous ulcers.
Methods: Four kits used to provide limb compression in the management of venous ulcers were evaluated. These have been proven to be non-inferior to various types of bandages in clinical trials. The interface pressure exerted above the ankle by the under-stocking and the complete compression system and the force required to pull the over-stocking off were assessed *in vitro*. Ease of application of the four kits was evaluated in four sessions by five nurses who put stockings on their own legs in a blinded manner. They expressed their assessment of the stockings using a series of visual analogue scales (VASs).
Results: The Sigvaris Ulcer X® kit provided a mean interface pressure of 46 mmHg and required a force in the range of 60–90 N to remove it. The Mediven® ulcer kit exerted the same pressure but required force in the range of 150–190 N to remove it. Two kits (SurePress® Comfort and VenoTrain® Ulcertec) exerted a mean pressure of only 25 mmHg and needed a force in the range of 100–160 N to remove them. Nurses judged the Ulcer X and SurePress kits easiest to apply. Application of the VenoTrain kit was found slightly more difficult. The Mediven kit was judged to be difficult to use.
Conclusions: Comparison of ease of application of compression-stocking kits in normal legs revealed marked differences between them. Only one system exerted a high pressure and was easy to apply. Direct comparison of these compression kits in leg-ulcer patients is required to assess whether our laboratory findings correlate with patient compliance and ulcer healing.

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Venous ulcers are traditionally treated with leg compression. Application of short-stretch bandages in multiple layers providing an interface pressure at the ankle of at least 40 mmHg has been recommended.[1,2] However, several randomised clinical trials and a meta-analysis have shown that medical compression stockings (MCS) are equivalent to or even better than various kinds of bandages regarding both the proportion of ulcers healed and time to healing.[3–11] MCS showed clear benefits as compared to bandages: less pain, better improvement in quality of life, higher patient acceptability, easier handling and less use of nursing time. However, the practicality of application and removal of MCS has not been investigated in direct comparisons. The ease with which MCS can be applied and removed in the treatment of leg ulcers will determine patient compliance and success of treatment.

Four two-piece, graduated, compression systems produced better results than bandages in comparisons of ease of use and various subjective factors.[3] The systems are marketed as sets consisting of an under-stocking or liner which is easy to apply, keeps the dressing in place and exerts moderate elastic compression to the ulcer area. The under-stocking is left on the leg day and night and removed for wound treatment only. The second and stronger stocking is pulled over the under-stocking each morning and taken off in the evening.

We measured, *in vitro*, the pressure exerted by both the under-stocking and the complete compression kit and determined the force required to pull off the over-stocking. We also asked nurses at the wound-treatment centre to study the ease of application of each component to their own legs.

Methods

Stocking systems

Four two-piece, graduated, compression systems, all of calf length, were included in these tests: #1: VenoTrain® Ulcertec (Bauerfeind AG, Oberrohrdorf, Switzerland); #2: SurePress® Comfort™Pro (ConvaTec Limited, Ickenham, Uxbridge, UK); #3: Mediven® Ulcer Kit (Medi, Bayreuth, Germany) and #4: Sigvaris® Ulcer X® (Ganzoni & Cie AG, St.Gallen, Switzerland). The Ulcer X kit was provided by the manufacturer, the other stockings were bought from medical retailers in Switzerland (VenoTrain and Mediven) and England (SurePress). Foot-slips and other aids are provided with the kits or recommended for separate purchase for easier application. None of these was used in the study.

Measurements in the laboratory of textile engineering

In vitro experiments were performed in the laboratory of textile engineering (Sigvaris, Saint-Just-Saint-Rambert, France) on a healthy volunteer. Two series of measurements were performed with each stocking system. First, the pressure exerted at rest in the area above the ankle was assessed with the dynamometer (Zwick-type Z005, Zwick GmbH&Co, Ulm, Germany) applying French Norm NF G30102b.[12] We assessed the liner and stocking separately, then the system as a whole. Each product was tested 3 times and the mean value (standard deviation (SD)) recorded.

A second series of experiments was performed to quantify the friction factor. Friction factor is the term used to summarise the surface properties of the garments in contact with the skin and each other. This determines the ease of sliding the liner over the skin and dressing and the over-stocking over the liner. As no norm or recommendation exists on how to evaluate the application of MCS, a method was devised at the Sigvaris research and development laboratory again using the Zwick-type Z005 dynamometer. A healthy volunteer was asked to apply the compression system as explained in the leaflet accompanying the kit. He then sat in front of the dynamometer and straightened his leg towards the instrument. The toe part of the outer stocking was attached to the dynamometer with a flexible, inelastic tape. The stocking was then pulled off the leg and foot at a speed of 50 cm min^{-1} and the force required to achieve this was recorded in newtons. Tests were repeated 3 times for each product under identical conditions: same volunteer, operator, room temperature and humidity and equipment settings. The results were expressed giving the whole data range. The force necessary to pull off the stocking was assumed to be similar to the force required to put it on. No instrument exists to measure the forces needed to put on a stocking. Fig. 1 shows the test person in front of the dynamometer prepared to measure the force required to remove the MCS.

Assessment of ease of application and comfort by nursing staff

Five nurses experienced in treating patients using compression therapy tested the performance of the four systems by putting the stockings on their own legs in a blinded manner. The stockings were sized correctly for the nurses' legs. Blinding was achieved by removing all visible tags and labels. Four test sessions were scheduled on different days, at various times of the day and at least 2 days apart. Each stocking system was applied once by each of the five nurses at

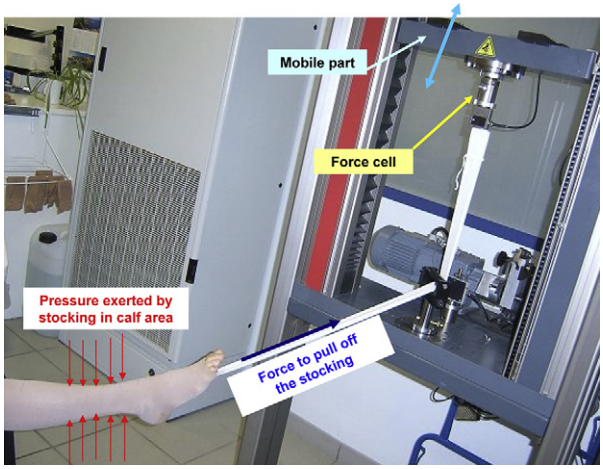

Figure 1 Dynamometer for *in vitro* assessment of pulling force to pull of a stocking.

each of the four sessions. To simulate a wound dressing, a rubber foam pad (3 M, Reston Products®) of 3 × 3 cm was applied above and behind the medial malleolus which is the typical of the location of a venous ulcer. If the 'wound dressing' was displaced by any stocking, it was replaced by a new dressing before testing the next system. The stockings were given to the nurses in random order. Appropriate handling was supervised by a second nurse who was also unaware of which product was being used. Six visual analogue scales (range: 0—10, 0 = very poor, 10 = very satisfactory) were completed immediately after each application. Two questions were asked about the feel of the stocking and its comfort against skin and four on its ease of application (Table 1). The ease of application score was calculated as the average of the first four items (Table 1).

Ethics

As stocking systems are categorised as a medical adjunctive device and the trial was performed with healthy volunteers, the approval of the local ethical committee was not required by our institutional review board.

Statistics

To test intra- and inter-volunteer reliability, Cronbach α-values were calculated. Cronbach α was also used to check the inter-item reliability of the four items used to compute the application convenience score. To compare the different stockings, a two-way analysis of variance (ANOVA) was calculated using stocking, nurse and their interaction effect as independent and rating as dependent variables (data not shown). Since the nurse effect was much smaller than the stocking effect and no interaction effect was detectable, one-way ANOVA with *post hoc* analysis and Bonferroni correction was used to compare the scores for the different stockings. The ease of application score was presented in error bars and 95% confidence intervals (CIs) for under- and over-stocking separately (Fig. 2).

Results

In vitro measurements of interface pressures and application forces

The static interface pressure exerted at the ankle area by the complete kit averaged 25 mmHg with stockings #1 and #2, and 46 with stockings #3 and #4. The under-stocking of kit #3 exerted a pressure as high as the pressure of the complete compression kits #1 and #2 (Table 2). The force required to pull off the over-stocking was low with kit #4, intermediate with kits #2 and #3 and very high with kit #1 (Table 2).

Table 1 Questionnaire to assess ease of application and comfort of stocking. The questionnaire was presented to each nurse at each visit and filled out separately for application of under-stocking and over-stocking. Visual analogue scale range: 0—10.

1 Application over the forefoot is (0 = difficult/10 = easy)
2 Application over the heel is (0 = difficult/10 = easy)
3 Wound dressing is displaced while lifting the stocking up: (0 = much/10 = not at all)
4 Dressing is 0 = difficult/10 = easy
5 The touch is 0 = rough/10 = delicate

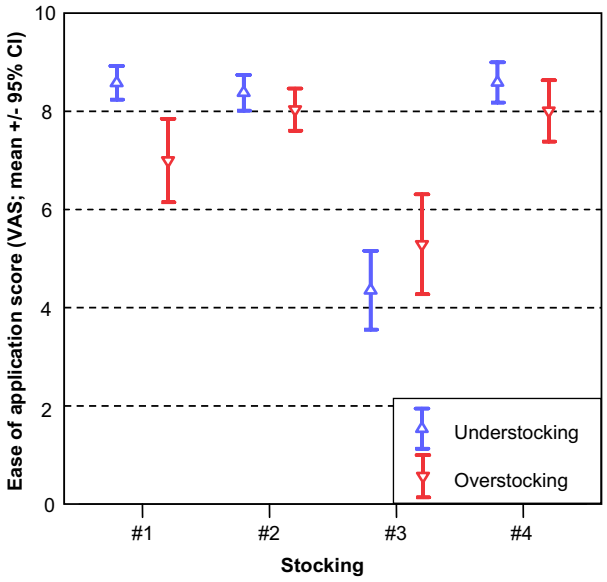

Figure 2 Ease of application score for under-stocking and over-stocking of each graduated compression system. Name and origin of stockings #1, #2, #3 and #4 are defined under methods.

Subjective assessment of application and comfort of the stocking systems

The assessment of repeatability of the these measurements demonstrated that consistent scores were obtained: the rating of the performance of a particular stocking by the same nurse across four tests showed little variation (Cronbach α for under-stocking: 0.95, for over-stocking: 0.90, respectively). The difference between observers was small for the under-stocking (Cronbach α: 0.95) and still acceptable for the over-stocking (Cronbach α: 0.79). The inter-item reliability of the four items composing the ease of application score was high (Cronbach α: 0.93).

All items showed significant differences between the under- and over-stockings (Table 3). Except for the touch of over-stocking kit #3 showed the poorest results at all other items. Garment touch and feeling on the leg revealed best ratings for over-stocking #2 and the poorest for over-stocking #4. Fig. 2 shows the results of the ease of application score.

Discussion

The stocking systems tested in this series for their ease of application have been studied previously in randomised trials against bandages to assess their ability to heal venous ulcers. Treatment with these stockings revealed a mean healing rate of 61% whereas bandages showed a healing

Table 2 Measurements of static interface pressure for each stocking component and force required to pull the over-stocking off the leg. Static interface is given in mmHg and S.D. Pulling force is given as a range referring to the minimum and maximum force which was measured during the process of pulling off the stocking.

Stocking system #	Static interface pressure above ankle. Mean pressure in mmHg (SD)			Pulling force (Newton)
	Understocking alone	Overstocking alone	Complete kit	Range min—max
1	7 (1.5)	18 (2)	25 (2)	150—190 N
2	9 (1.5)	15 (2)	24 (2)	100—140 N
3	24 (2)	22 (2)	46 (3)	100—160 N
4	17(2)	29 (2)	46 (3)	60—90 N

rate of only 27%.[3] Three of the four compression systems were also evaluated for ease of use and patient acceptability in these trials and received general approval concerning ease of use and comfort.

This study aimed to compare the ease of application of the four compression systems in a group of volunteers who were also health-care professionals. Two compression systems (#1 and #2) did not exert the recommended level of compression although they had shown a higher proportion of healing in comparison with bandages in the randomised controlled trials.[6,8] Of the two systems exerting the recommended pressure, one was very difficult to apply to the limb (#3). The foot-slip supplied with the kit was not used in the application experiments. When we used it off protocol for *in vitro* tests, we found reduced force was required to remove the over-stocking from the leg. The force was reduced from 150—180 N to 100—140 N. It must be noted that, in practice, this slip can only be used to put on the stocking and not to pull it off. System #4 required the least pulling force, produced the amount of static interface pressure believed to be necessary to secure ulcer healing and ranked high in the nurses' tests.

The findings of the *in vitro* tests and the estimates made by the nurses were unequivocal and consistent. Extending our study to involve trials in patients was beyond our limited intentions in this investigation. It would be useful to obtain a comparison of interface pressures, ease of application and use of the compression systems and efficacy of healing in a clinical trial. This would be a much larger investigation than the limited scope of our study.

In conclusion, this study compared four compression systems for use in the management of venous ulceration from different manufacturers which comprised a two-piece, graduated, compression system. All systems have established efficacy in healing venous ulcers. Two systems provided the recommended interface pressure and were easy to put on and pull off. Two other systems had similar clinical efficacy and ease of application but provided much lower compression. We have not attempted to assess the relative efficacy of these compression systems in healing leg ulcers, so we have not established that the lower interface-pressure measurements have any clinical implications. One kit was difficult to apply and remove and cannot be recommended.

Table 3 Ease of application score and single VAS items: mean values (SD), ANOVA F, and significant Bonferroni corrected post hoc comparisons.

Stocking	Ease of application score	Application over forefoot	Application over heel	Wound dressing in place	Ease of dressing	Touch smooth-ness	Comfort on legs
Understocking							
#1	8.6 (0.7)	8.9 (0.8)	8.8 (0.7)	8.4 (0.9)	8.2 (1.1)	6.8 (2.4)	7.7 (1.7)
#2	8.4 (0.8)	8.6 (0.8)	8.4 (0.9)	8.1 (1.0)	8.4 (0.8)	7.9 (1.7)	7.9 (1.2)
#3	4.4 (1.7)	3.7 (2.4)	4.2 (1.9)	3.4 (2.3)	6.1 (1.7)	3.9 (2.3)	5.2 (2.0)
#4	8.6 (0.9)	8.9 (0.8)	8.6 (1.0)	7.9 (1.5)	8.9 (0.9)	8.9 (0.9)	8.0 (1.6)
F (p)	71.6***	68.2***	65.0***	49.5***	21.3***	25.3***	13.2***
Post hoc	#(1,2,4) > #3	#(1,2,4) > #3	#(1,2,4) > #3	#(1,2,4) > #3	#(1,2,4) > #3	#(1,2,4) > #3 #4 > #1	#(1,2,4) > #3
Overstocking							
#1	7.0 (1.8)	6.8 (2.4)	6.6 (2.5)	7.0 (2.2)	7.6 (1.7)	5.7 (2.3)	7.7 (1.4)
#2	8.0 (0.9)	7.9 (1.5)	7.9 (1.1)	8.1 (1.0)	8.1 (0.9)	8.0 (1.4)	7.5 (1.5)
#3	5.3 (2.2)	4.8 (2.5)	5.0 (2.2)	5.4 (2.8)	6.1 (2.1)	6.7 (1.8)	5.7 (1.9)
#4	8.0 (1.3)	7.7 (1.9)	7.8 (1.9)	8.3 (0.9)	8.2 (0.9)	4.1 (2.0)	7.4 (1.4)
F (p)	12.5***	9.5***	9.6***	9.9***	8.6***	14.5***	7.7***
Post hoc	#(1,2,4) > #3	#(2,4) > #3	#(2,4) > #3	#(1,2,4) > #3	#(1,2,4) > #3	#(2,3) > #4 #2 > #1	#(1,2,4) > #3

***$p < .001$.

Conflict of Interest

The following conflicts of interest are stated:
Torsten Willenberg: No conflict of interest.
Bertran Lun: Textile engineer of Sigvaris France.
Felix Amsler: Scientific consultant Sigvaris Switzerland.
Iris Baumgartner: No conflict of interest.

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