Donning Devices (Foot Slips and Frames) Enable Elderly People with Severe Chronic Venous Insufficiency to put on Compression Stockings

K. Sippel a,*, B. Seifert b, J. Hafner a

a Department of Dermatology, University Hospital of Zurich, Gloriastrasse 31, CH-8091 Zurich, Switzerland
b Division of Biostatistics, Institute for Social and Preventive Medicine, University of Zurich, Zurich, Switzerland

WHAT THIS PAPER ADDS
This study is the first to examine the ability of “real” elderly patients with chronic venous insufficiency to don compression stockings, and the first to demonstrate the benefits of donning devices. The results might contribute to improving the implementation of compression therapy carried out by patients.

INTRODUCTION
Medical compression therapy of the lower leg is effective for the treatment, and perhaps also in the prevention, of post-thrombotic syndrome (PTS), for the treatment, and perhaps also in the prevention, of active venous leg ulcer (VLU), and in preventing the recurrence of VLU. Compression of the lower leg is also effective in the improvement of symptoms of chronic venous insufficiency (CVI), reduction of edema, tension and pain, and in improving quality of life.

Objective/background: Compression therapy is highly effective in the treatment of post-thrombotic syndrome and venous leg ulcer. On average, 50–60% of the patients cooperate with compression therapy. Therefore, it is necessary to improve the user-friendliness. This prospective study investigated whether the use of donning devices can contribute to improving user-friendliness.

Methods: Forty patients aged >65 years with severe chronic venous insufficiency (CVI; C4–C6) successively donned compression stockings in a randomized order: one 40 mmHg (CS40) or two superimposed 20 mmHg (CS20+20), each with open toe (CS-o-t) and closed toe (CS-c-t), using donning devices (three foot slips for CS-o-t; two foot slips and three frames for CS-c-t). The study endpoint was that the stocking was completely donned and correctly positioned on the patient’s leg. The success rate and its association with age, sex, first time versus second time user, body mass index, abdominal circumference, ability to reach the forefoot with the hand, and hand grip strength were analyzed. Additionally, subjective evaluation by the patients was performed.

Results: Without donning devices, success with CS40-c-t was 60% (24/40 patients) and with CS20+20-c-t 70% (28/40 patients) (p = .220). Using donning devices increased success rates significantly. With CS40-o-t the success rate was 88% (35/40 patients; p = .001) and with CS40-c-t it was 90% (36/40 patients; p = .002). With CS20+20-o-t and CS20+20-c-t, the success rate was 88% (35/40 patients; p = .016). The proportion of patients who successfully used either CS40 or CS20+20 increased from 73% to 93%. Relevant for the patients’ success was the ability to reach the forefoot with the hand, and hand grip strength. Subjectively, donning with a device was rated significantly better than without.

Conclusion: Donning devices significantly improve the ability of elderly patients with CVI to don compression stockings successfully. However, there are differences in user-friendliness among the devices.

According to the literature, compression stockings are not inferior to compression bandages in effectiveness for most indications. Compression stockings offer the advantage that patients can apply them on their own leg more easily than bandages. Once applied, they guarantee a pre-determined pressure, which remains constant throughout the day. Although the application of a medical compression stocking seems to be simple, approximately 40% (range 20–80%) of patients with a clear indication for compression therapy did not carry out the treatment. When asked why, the patients gave different reasons for not wanting or not being able to implement compression therapy. The main reasons given were difficulties in donning the stocking, eczema, dry skin, itchiness, constriction, and laziness. With regard to difficulties in donning the stockings, common
reasons were age, inability to reach the feet with the hands, and obesity.\textsuperscript{10,13} In this study, it was hypothesized that medical donning devices could probably make it easier for elderly patients with CVI to put on compression stockings. The aim was to examine how many “real” patients with CVI aged >65 years succeed in donning stockings of different compression strength, trying without any device or with various models of medical donning devices.

**METHODS**

**Ethics**

The study was approved by the ethics commission of the Canton of Zurich (KEK-ZH2010-0329/5) and registered at clinicaltrials.gov (NCT01432795). It was performed according to the Declaration of Helsinki and the good clinical practice guidelines of the Clinical Trial Centre of the University Hospital of Zurich. All patients were given oral and written information about the aims and design of the study, and gave their written consent.

**Study design**

The study design was a prospective comparative application study. Application success with compression stockings was tested on patients using different donning devices already on the market.

**Patients**

According to sample size calculation, 40 patients aged >65 years with severe CVI (C4–C6) were recruited at the hospital after phlebological examination by the study leader (K.S.). Inclusion criteria were age >65 years, CIV C4–C6 (thus qualifying for compression therapy), and patient consent. Exclusion criteria were VLW with a surface area >5 cm\(^2\), peripheral artery occlusive disease with an ankle-brachial index (ABI) <0.75, visual impairment with corrected eyesight <0.8, restricted mobility due to a neurological condition (all types of paresis or plegia), and developing dementia (pathological mini-mental test).

**Compression stockings used in the study**

A Cotton 223 A-D stocking (SIGVARIS, Winterthur, Switzerland) was used with a compression strength of 34–46 mmHg (compression class 3 according to the European Committee for Standardization [CEN]), with an open toe (CS40-open-toe) and with a closed toe (CS40-closed-toe). These were considered “strong” compression stockings.

A Venosan 5001 A-D stocking (SALZMANN MEDICO, St. Gallen, Switzerland) was used with a compression strength of 18–21 mmHg (compression class 1 according to CEN), with an open toe (CS20+20-open-toe) and with a closed toe (CS20+20-closed-toe). These were considered “light” compression stockings.

**Donning devices (foot slips and frames) used in the study**

An Easy Slide (SIGVARIS; Fig. 1A), Veno Glider (SALZMANN; Fig. 1B), and a Venotrain “Blue” Foot Slip (Bauerfeind, Oberrohrdorf, Switzerland; Fig. 1C) were used for compression stockings with open toe (CS-open-toe).

An Easy Slide Caran (SIGVARIS; Fig. 1D) and a Venotrain Glider (Bauerfeind; Fig. 1E) were used for compression stockings with a closed toe (CS-closed-toe).

A Socks Jet frame with and without a handle (SALZMANN; Fig. 1F, G) and a Mediven Butler frame (MEDI, Bayreuth, Germany; Fig. 1H) were used for CS-closed-toe.

**Study protocol**

All patients had their legs measured by the study leader (K.S.) and were then provided with new compression stockings. Donning devices were offered to the patients. Each donning attempt by the patient was preceded by an exact instruction including demonstration, and supervised by the study leader (K.S.). At first, the patients attempted to put on a CS40-closed-toe stocking (one donning attempt) and the superimposed stockings CS20+20-closed-toe (one donning attempt) without using a donning device. Next, the eight donning devices were tested in a randomized order using CS40-closed-toe (five devices, five donning attempts), CS40-open-toe (three devices, three donning attempts), CS20+20-closed-toe (five devices, five donning attempts), or CS20+20-open-toe (three devices, three donning attempts). Randomization was achieved by letting the patient draw numbered cards, each indicating one donning process. Every patient performed 18 donning attempts with a total of 27 stockings. The primary endpoint of the study was a successful donning attempt, which was defined as one CS40 stocking or two CS20+20 superimposed stockings, completely donned and correctly positioned on the patient’s leg (“ready-to-wear”) (Time required was not taken into account.) Furthermore, a subjective scoring of the donning attempt by the patient was assessed (secondary endpoint). For scoring, Swiss schools marks 1 (worst) to 6 (very good) were used. Additionally, the following patient-related parameters were systematically recorded by the study leader (K.S.) and later associated with the objective success rate of the donning procedure: age, sex, first- versus second-time user of compression stockings, body mass index (BMI), abdominal circumference, ability to reach the foot with the hand, and grip strength as measured by vigorimetry.\textsuperscript{22}

**Statistics**

The number of patients was chosen with the assumption that 50% of patients would succeed in putting on a compression stocking without a donning device, and that this percentage would increase to 80% with the use of a donning device. With this assumption, the exact McNemar test (using binomial distribution) has 83% power at a .006 two-sided significance level, when the sample size is 40 pairs and the proportion of discordant pairs is expected to be 31%.  

K. Sippel et al.
Figure 1. Donning devices (foot slips and frames). Foot slips for stockings with open toe: (A) Easy Slide (SIGVARIS, Winterthur, Switzerland); (B) Veno Glider (SALZMANN MEDICO, St. Gallen, Switzerland); (C) Venotrain Foot Slip (Bauerfeind, Oberrohrdorf, Switzerland). Foot slips for stockings with closed toe: (D) Easy Slide Caran (SIGVARIS) and (E) Venotrain Glider (Bauerfeind). Frames for stockings with open and closed toe stockings respectively: (F) Socks Jet without handle (SALZMANN); (G) Socks Jet with handle (SALZMANN) and (H) Mediven Butler (MEDI, Bayreuth, Germany).
Binary data were compared between different donning attempts using the McNemar test with exact p-values. Continuous and grading variables were presented as mean ± SD and compared between different donning attempts using the Wilcoxon signed ranks test with exact p-values. The effect of patient characteristics on the number of successful donning attempts was assessed using the Mann–Whitney test for binary and Spearman’s rank correlation for continuous data.

Two-sided p-values of <.050 were considered statistically significant. The Bonferroni correction was used when different donning attempts were compared. Because eight donning devices were compared with the attempt without device in each family of tests, a p-value ≤ .006 was considered statistically significant in these comparisons. The effect of patient characteristics on the number of successful donning attempts was analyzed separately for attempts without and with donning devices. Hence, p-values of <.025 were considered significant in these analyses, and <.013 if separate analyses were performed for men and women.

SPSS Statistics version 20 (IBM, Armonk, NY, USA) was used for statistical analyses.

RESULTS

The 40 patients enrolled in the study had a mean age 78.7 ± 6.4 years (range 66.0–92.0 years, median 78.0 years). There were 23 women (57.5%) and 17 men (42.5%). Twenty-seven patients were classified as C4, eight C5 and five as C6. The patients performed a total of 720 donning attempts.

Objective donning success

Without a donning device, 60% (24/40) of patients were able to put on the CS40-closed-toe stocking and 70% (28/40) of patients were able to put on the combination of CS20+20-closed-toe stockings (p = .220, McNemar test). In total, 73% (29/40) of patients managed to don either the CS40-closed-toe or CS20+20-closed-toe stockings without any donning device.

With the aid of donning devices, the number of “successful” patients increased to 93% (37/40) (p = .008, McNemar test). These patients could either put on at least one CS40 (closed-toe or open-toe) or at least one CS20+20 (closed-toe or open-toe). The proportion of “non-successful” patients who could not don any stocking was reduced to 8% (3/40) (Table 1).

The success rates with each donning device and stocking type are shown in Fig. 2. With five of eight donning devices a higher donning success rate could be reached than without any donning device.

Two of the three foot slips for CS-open-toe stockings enabled the patients to put on the “strong” CS40-open-toe stocking significantly more often than without donning device (p = .001 and p = .002, respectively). One of the two foot slips for CS-closed-toe stockings and one of the three frames enabled the patients to put on the “strong” CS40-closed-toe stockings significantly more often than without a donning device (p = .002). The success rates of the donning attempts are shown in Fig. 2A. Two of the three foot slips for CS-open-toe stockings enabled the patients to put on the two “light” superimposed CS20+20-open-toe stockings, one over the other on the same leg, more often than without a donning device (p = .016 and p = .030, respectively). One of the two foot slips for CS-closed-toe stockings and one of the three frames enabled the patients to put on the two “light” CS20+20-closed-toe stockings more often than without a donning device (p = .010 and p = .040, respectively). (For CS20+20, differences did not turn out to be significant in the test because without a donning device the success rate was already higher than for CS40). Success rates of donning attempts are given in Fig. 2B (For some donning devices the success rate was lower than the success rate without any donning device because they were not suitable for every foot shape.)

Patient related parameters and donning success

There was an association between the objective success rate achieved by patients without any donning device and both forefoot reach with the hands (p = .001) and hand grip strength (p = .003). There was no association with non-first time users. Only in the subgroup CS40-closed-toe, did statistical calculation show a slight association with non-first time users. The only parameter associated with donning success using donning devices was forefoot reach with the hands (p = .001). There was no relevant association with non-first time users. For the patient related parameters sex, age, BMI, and abdominal circumference, no association with success rate was found neither with nor without a donning device (Table 2).

Subjective evaluation

In the subjective evaluation of donning processes by the patient, donning of stockings without a donning device was graded with a low (unsatisfactory) mark, both in donning a “strong” CS40-closed-toe stocking and in donning two superimposed “light” CS20+20-closed-toe stockings (p = .290, Wilcoxon signed ranks test).

Donning of stockings with the aid of donning devices was generally graded better than without. Regarding “strong” CS40 stockings, a significantly better average grade compared with donning without any device was shown for the following devices: all three foot slips for CS-open-toe, one of the two foot slips for CS-closed-toe, and two of the three frames (Fig. 3A). Likewise, regarding the superimposed “light” CS20+20 stockings, a significantly better average grade compared with donning without any device was shown for all three foot slips for CS-open-toe stockings, one of the two foot slips for CS-closed-toe stockings, and two of the three frames (Fig. 3B). In the subjective grading of donning devices there tended to be favorites. Individual patient evaluation, however, varied greatly (Fig. 4).
Table 1. Number of patients \((n = 40)\) that (at least once) successfully donned either CS40 or CS20\(^{+20}\) stockings without any device, or with at least one of the eight donning devices.

<table>
<thead>
<tr>
<th>Only without device</th>
<th>0 [ 0 %]</th>
<th><strong>Total without device</strong></th>
<th>29 [73 %]</th>
<th><strong>Total with device</strong></th>
<th>37 [93 %]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Without device and with device</td>
<td>29 [73 %]</td>
<td><strong>Total with device</strong></td>
<td>29 [73 %]</td>
<td><strong>Total with device</strong></td>
<td>37 [93 %]</td>
</tr>
<tr>
<td>Only with device</td>
<td>8 [20 %]</td>
<td><strong>Total with device</strong></td>
<td>29 [73 %]</td>
<td><strong>Total with device</strong></td>
<td>37 [93 %]</td>
</tr>
<tr>
<td>Neither with nor without device</td>
<td>3 [ 8 %]</td>
<td><strong>Total with device</strong></td>
<td>29 [73 %]</td>
<td><strong>Total with device</strong></td>
<td>37 [93 %]</td>
</tr>
</tbody>
</table>

Figure 2. Patient success rates for each donning device. Success rate: successfully accomplished donning attempts out of 40 [%]. Comparison of the success rates with each donning device to the success rate without any device by McNemar test. After Bonferroni correction, \(p\)-values \(\leq 0.006\) are significant. * Significantly better results; \(\circ\) Better results with distinct trend. - Better results with certain tendency. (A) 40 mmHg stocking (CS40); (B) superimposed 20 mmHg stockings (CS 20\(^{+20}\)).

![Table 1](image1)

![Figure 2](image2)
To the authors’ knowledge, this is the first study to examine the ability of “real” elderly patients with CVI to don compression stockings, and the first to demonstrate the benefits of donning devices. The patients included in the study had C4—C6 CVI and thus had a clear indication for compression therapy and would benefit from wearing compression stockings. According to the Bonn Vein Study, the prescription frequency of medical compression stockings increases with a higher CEAP classification (55% in C4 patients vs. 82% in C5/C6 patients). As the therapeutic superiority of compression stockings for the treatment of VLU compared with compression bandages is especially true for VLU <5 cm², only patients with VLU <5 cm were included. Concerning choice of compression class, major randomized controlled trials (RCTs) have been performed with 40 mmHg compression. The studies on prevention of PTS were performed with stockings with a compression level of 30 mmHg. A RCT on the prevention of recurrent VLU was performed using stockings with a compression level of 30 versus 20 mmHg. Generally, for all forms of severe CVI (C4—C6), the highest pressure that can be tolerated by the patient is recommended. Thus, when the peripheral arterial circulation is normal or mildly impaired (ABI > 0.75), a compression strength of 40 mmHg (CEN compression class 3) can be recommended. Assuming that lower compression stockings are easier to put on, pulling one lower compression stocking over another is sometimes recommended (superimposed stockings). Therefore, in this study, one strong (40 mmHg) stocking and two superimposed light (20 mmHg) stockings were chosen. Therefore, patients who managed to don either one strong (40 mmHg) stocking or two superimposed light (20 mmHg) stockings would be deemed successful in putting on a compression stocking with a strength matching their CEAP class. Regarding donning devices, the assortment available on the market was considered and devices from each category (foot slips and frames) were chosen.

In this study, donning devices enabled older patients with severe CVI to successfully put on lower leg compression stockings more often than without any device. In this study, the increase in the proportion of “successful” patients (those able to put on either CS40 or CS20+20 stockings) from 73% to 93% was statistically significant.

### Table 2. Influence of patient related parameters on donning success rate.

| Parameters (occurrence within patient group [n = 40]), n (%) | Association with donning success CS40 or CS20+20 Without donning device With donning device p |
|------------------------------------------------------------|-------------------------------------------------|-----------------------------------------------|
| Sex, female                                                | Association with donning success                | p                                             |
| Female                                                     | CS40 or CS20+20                                 | Without donning device                        | With donning device |
| 23 (57)                                                    | .590⁴                                           | .840⁴                                         |
| Male                                                       | .042¹,²                                          | .550⁴                                         |
| First time user                                            |                                                  |                                               |
| Yes                                                        | .001⁴,⁵                                         | .001⁴,⁵                                       |
| No                                                         | .001⁴,⁵                                         | .001⁴,⁵                                       |
| Age (y)                                                    | Association with donning success                | p                                             |
| Range                                                      | .180⁴                                           | .280⁴                                         |
| Mean ± SD                                                  | .930⁴,⁵                                         | .740⁴,⁵                                       |
| Median                                                     | 78                                              |                                               |
| BMI (%)                                                    | Association with donning success                | p                                             |
| Mean ± SD                                                  | .003⁴,⁵                                         | .063⁴                                         |
| ≥25                                                        | 63                                              |                                               |
| 25—29                                                      | 43                                              |                                               |
| ≥30                                                        | 20                                              |                                               |
| Abdominal circumference (cm)                               | Association with donning success                | p                                             |
| Range                                                      | .140⁴                                           | .120⁴                                         |
| Mean ± SD                                                  | 104.7 ± 11.6                                    |                                               |

**Note.** Donning success rate is defined here as the total number of successfully donned C40 or CS20+20 stockings per patient after completion of all scheduled donning processes according to the protocol.

- Calculation of a possible association of the patient characteristics with donning success by Mann–Whitney test for non-continuous/binary variables.
- Nearly significant association for subgroup CS40 (p = .010), not for CS20+20 (p = .424).
- Calculation of a possible association of the patient characteristics with donning success by Spearman’s test for continuous variables.
- As there was no association, subgroups were not calculated separately.
- Significant association.

### DISCUSSION

To the authors’ knowledge, this is the first study to examine the ability of “real” elderly patients with CVI to don compression stockings, and the first to demonstrate the benefits of donning devices. The patients included in the study had C4—C6 CVI and thus had a clear indication for compression therapy and would benefit from wearing compression stockings. According to the Bonn Vein Study, the prescription frequency of medical compression stockings increases with a higher CEAP classification (55% in C4 patients vs. 82% in C5/C6 patients). As the therapeutic superiority of compression stockings for the treatment of VLU compared with compression bandages is especially true for VLU <5 cm², only patients with VLU <5 cm were included. Concerning choice of compression class, major randomized controlled trials (RCTs) have been performed with 40 mmHg compression. The studies on prevention of PTS were performed with stockings with a compression level of 30 mmHg. A RCT on the prevention of recurrent VLU was performed using stockings with a compression level of 30 versus 20 mmHg. Generally, for all forms of severe CVI (C4—C6), the highest pressure that can be tolerated by the patient is recommended. Thus, when the peripheral arterial circulation is normal or mildly impaired (ABI > 0.75), a compression strength of 40 mmHg (CEN compression class 3) can be recommended. Assuming that lower compression stockings are easier to put on, pulling one lower compression stocking over another is sometimes recommended (superimposed stockings). Therefore, in this study, one strong (40 mmHg) stocking and two superimposed light (20 mmHg) stockings were chosen. Therefore, patients who managed to don either one strong (40 mmHg) stocking or two superimposed light (20 mmHg) stockings would be deemed successful in putting on a compression stocking with a strength matching their CEAP class. Regarding donning devices, the assortment available on the market was considered and devices from each category (foot slips and frames) were chosen.

In this study, donning devices enabled older patients with severe CVI to successfully put on lower leg compression stockings more often than without any device. In this study, the increase in the proportion of “successful” patients (those able to put on either CS40 or CS20+20 stockings) from 73% to 93% was statistically significant.
However, not all foot slips or frames performed equally effectively compared with no donning device. Of the donning devices for open toe stockings, two particularly effective foot slips were identified. Of the donning devices for closed toe stockings, one particularly effective foot slip and one particularly effective frame were identified. However it is not possible to predict whether an individual patient will cope better with a foot slip or a frame. Overall regarding patients’ success rates with each donning device, it can be said, that 85–90% of patients with CVI will be able to don a lower leg compression stocking correctly on their own with the help of a donning device, whereas the success rate without a donning device is about 60–70%.

The use of a stocking system of two superimposed “light” lower leg compression stockings each with a pressure of 20 mmHg compared with a single “strong” compression stocking with a pressure of 40 mmHg was associated with a slight improvement in donning success rate (70% vs. 60%). However, the difference was not significant, therefore in this study it was not easier for patients to put on the two “light” superimposed stockings than to put on the one “strong” stocking.

Of those patient related parameters, of which a possible influence on the donning success is postulated, this study showed a significant association with donning success for the parameter “reach the forefoot with the hand”, as well as for the parameter “hand grip strength”. When donning devices were used, the parameter “hand grip strength” lost its relevance.

Using donning devices, the proportion of “non-successful” patients who could not don any stocking was reduced to 7.5%. These patients showed both of the relevant parameters: they could not reach the forefoot with the hand and they had a reduced hand grip strength compared with the mean value of the study population. Additionally, they

![Figure 3. Patient evaluation of each donning device. Evaluation: 1 = worst, 6 = very good. Comparison of the average scores with each donning device with the average score without any device by Wilcoxon Signed Ranks test. * Significantly better results. (A) 40 mmHg stocking (CS 40); (B) superimposed 20 mmHg stockings (CS 20+20).](image-url)
had a larger abdominal circumference compared with the mean value of the study population (however, statistical analysis regarding this observation was not possible because of the small number of patients).

Interestingly, there was no relevant association of the parameter “non-first time user” with the success rate. Of course, this was a parameter recorded by asking the patient. Nevertheless, the study leader’s observation on how study patients carried out their donning attempts was that one instruction and demonstration by the study leader allowed the patients to understand and perform the donning process. If patients did not succeed in donning the stocking it was because of physical patient related parameters. Although the order of donning attempts performed by each patient was randomized in order to compensate for a possible “training effect”, not one patient had more successful attempts at the end of the donning protocol than in the beginning. A relevant “training effect” is unlikely to be involved as the instruction was exactly as needed and preceded each donning attempt.

Figure 4. Variability of patient preferences in the subjective evaluation of donning devices. Subjective grading (marks 1—6) per donning device shown as box plots with median, 25th percentile, 75th percentile, minimum, and maximum. (A) 40 mmHg stocking (CS40); (B) superimposed 20 mmHg stockings (CS 20+20).
The study data show that after a single instruction at least 73% of patients [in a patient group with 68% first time users] were able to put on either a CS40 or two CS20+20 stockings without any donning device. It should again be noted that patients with visual impairment, all types of paresis or plegia, and developing dementia were excluded.

Finally, the patients’ subjective evaluation of the different donning devices did not result in any clear additional information. There seemed to be some favorites, but individual patient preferences varied greatly. Most patients had at least one preferred device. However, the use of a donning device was generally deemed helpful by the patients (including those who also were able to put on stockings without a device). Nevertheless, there is still room for new device design and further research in this area.

In conclusion, this study shows that donning devices (foot slips or frames) allow older patients with CVI to put on compression stockings and donning devices. The authors MEDICO for the generous provision of the required stockings without any donning device. It should again be noted that patients with visual impairment, all types of paresis or plegia, and developing dementia were excluded.

ACKNOWLEDGMENT

The project was awarded the SGP-Award 2010 by the Swiss Society of Phlebology. The authors thank (in alphabetical order) BAUERFEIND, GANZONI/SIGVARIS, and SALZMANN MEDICO for the generous provision of the required compression stockings and donning devices. The authors also thank the JH Rahn Foundation for their support.

REFERENCES