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

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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.

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.,

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INTRODUCTION

Medical compression therapy of the lower leg is effective for the treatment, and perhaps also in the prevention, of post-thrombotic syndrome (PTS),[1–4] for the treatment of active venous leg ulcer (VLU),[3–5] and in preventing the recurrence of VLU.[3,4,6] 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.[7–11]

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 predetermined 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.[6,12,13] 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

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reasons were age, inability to reach the feet with the hands, and obesity.[10,13–20]

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 according to the clinical, etiological, anatomical, and pathophysiological [CEAP] classification[21]) were recruited at the hospital after phlebological examination by the study leader (K.S.). Inclusion criteria were age >65 years, CVI C4–C6 (thus qualifying for compression therapy), and patient consent. Exclusion criteria were VLU 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 forefoot with the hand, and grip strength as measured by vigorimetry.[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%.