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A Compression Kit of a Stocking and Three Superimposed Leggings Is Easy to Don and Dose Adjustable

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WHAT THIS STUDY ADDS
A compression stocking kit composed of an understocking and superimposable leggings is easier to don.

Background: Forty percent of patients with chronic venous insufficiency (CVI) do not wear their indicated and prescribed compression stockings. Difficulties in donning and a feeling of constraint are the most common reasons for non-adherence.
Objective: The aim was to develop a compression stocking system that is easy to don and dose adjustable.
Methods: A modular compression stocking kit composed of an understocking and three superimposable leggings (SLLLs) was developed. Substocking pressures (*P*) at the thinnest part above the ankle (cB level) were 17 mm (understocking) + 15 + 10 + 10 mmHg (3 superimposed leggings; Hatra method). Twenty healthy subjects and 20 patients over 65 years with CVI donned the SLLL compression kit. *P* was measured in vivo (Picopress method) at the transition of the Achilles tendon to the calf muscle (level cB1) during rest and ankle movements (DSI; dynamic stiffness index) and compared with a strong compression stocking of 40 mmHg (S40).
Results: Twenty (20/20) patients aged over 65 with CVI (C4–6) successfully donned the SLLL compression kit without aid, compared with 12 (12/20) who were able to don the S40 without aid ($p = .02$). *In vivo* resting *P* at level cB1 was 34.3 mmHg (SLLL) compared with 37.3 mmHg (S40) ($p = .1$). The DSI was 16.1 (SLLL) compared with 17.9 ($p = .79$; S40; CVI group).
Conclusion: The physical properties of the SLLL compression stocking kit correspond to the characteristics of a strong stocking at rest and exercise (DSI). The donning success rate is excellent (100%). A further potential advantage is that the SLLL leg compression kit is dose adjustable, according to indication or patient tolerance. Wearing comfort over periods of several days and clinical effectiveness need to be investigated in future trials.

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INTRODUCTION

Compression therapy is pivotal in the treatment and prevention of chronic venous insufficiency (CVI). Its effectiveness in the treatment of venous leg ulcers (VLUs), prevention of VLU recurrence and of post-thrombotic syndrome (PTS) has been empirically proven by a number of high quality methodology clinical trials over the last two decades.[1–5] Moreover, compression therapy alleviates pain and improves quality of life.[6]

The advantages of compression stockings and multilayer compression bandages with an outer layer of a cohesive bandage are that they do not change their physical properties or lose interface pressure over one or more days of wear.[7,8] Stockings are as effective as compression bandages in the treatment of uncomplicated VLUs with a diameter <5 cm.[9] Several companies have developed ulcer stocking kits composed of a light understocking to be kept on day and night which keeps a wound dressing in place, combined with a strong overstocking which provides effective compression during the day. The overstocking glides more easily over the understocking than over skin. Despite the considerable technical progress in the production of compression materials, compliance with compression therapy has been found to be around 60%,[10,11] leaving a gap of 40% of patients who cannot or do not comply with compression therapy, the fundamental treatment of CVI. Difficulties in donning the stockings, a feeling of constraint,

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and dryness of skin are the three most common reasons given by non-compliant patients.[10]

In vitro, the substocking interface pressure (*P*) increases cumulatively with the superimposition of stockings.[12] Superimposing two light (20 mmHg) compression stockings, which would be easier to don, has therefore been suggested. In a recent study the donning success of this method under "real-world conditions" in patients over 65 with CVI, with a success rate improvement from 60% to 70%, was not statistically significant however.[11] Another recently presented solution is to divide the stocking at the ankle region into one part covering the foot and one part covering the lower leg with overlap in the ankle region.[13] Further stocking kits composed of an understocking and a compressive legging are available for long distance running.

PATIENTS AND METHODS

Stocking and superimposed leggings leg compression kit

The prototype presented (SIGVARIS AG, St. Gallen, Switzerland) is composed of an understocking which provides an in vitro *P* of 17 mmHg at the thinnest point above the ankle (level cB) as determined by the Hatra method.[14] The understocking is knitted in a degressive technique to reach 50—80% of pressure two fingers below the knee (level cD). Three superimposable leggings (L) add to the compression. L1 provides a *P* of 15 mmHg and L2 and L3 each provide a *P* of 10 mmHg at the cB level, as determined in vitro (Hatra) (Fig. 1). The leggings are also knitted in a degressive technique, reaching 50—80% of *P* at the level cD below the knee. As a control a strong ($P = 40$ mmHg at cB) leg compression stocking was used (S40) (Varisan Top Micro, Medileg SA, Domdidier, Switzerland).

Patients

Twenty healthy volunteers and 20 patients over 65 with CVI were recruited (C4 or C5 according to CEAP) so that the rates of successful donning and the physical properties of the SLLL system could be examined. Healthy volunteers were selected from staff physicians, residents, and students working in the department. Patients were selected at random during phlebology consultation, if they were interested in testing the new product and willing to participate in a clinical study. They had to be over 65 years old and suffer from clinical stage C4 or C5 (CEAP classification). Patients with peripheral arterial disease (defined as ankle—brachial index < 0.9) or polyneuropathy were excluded. See Table 1 for a summary of body mass index and comorbidities of the 20 enrolled patients.

To ensure a correct fit, leg circumference was measured by the first author at the thinnest point above the ankle (level cB) and two fingers below the knee (level cD), as was the distance from the sole of the heel to level cD of each participant. Data were transferred to SIGVARIS, where a knitting machine was specifically programmed to produce 40 SLLL leg compression kits in total, and according to the measures of each study participant.

Donning success

The first author instructed each study participant separately by demonstrating the donning procedure both with the strong stocking and the SLLL leg compression kit. The ability of healthy volunteers and patients to don the SLLL leg compression kit and the S40 stocking was assessed. A fully donned SLLL leg compression kit or S40 counted as donning success. Patients had as much time and as many attempts as required.

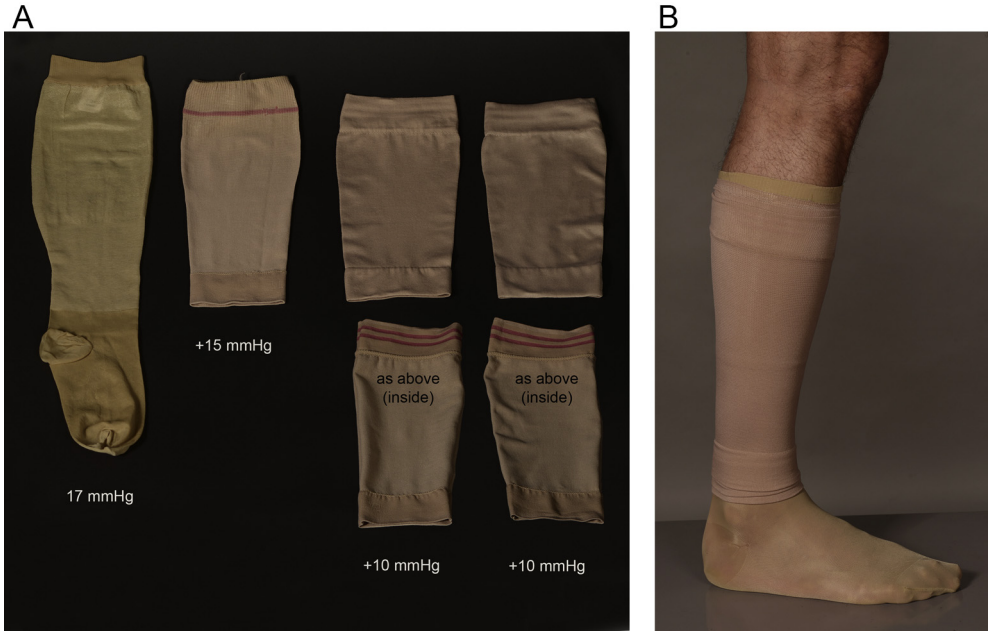

Figure 1. (A) The SLLL leg compression kit: understocking (17 mmHg at level B1) and three superimposable leggings (15 + 10 + 10 mmHg). (B) The SLLL leg compression kit fully donned.