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Immediate Hemodynamic Effect of the Additional Use of the SCD EXPRESS™ Compression System in Patients with Venous Ulcers Treated with the Four-layer Compression Bandaging System

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Objectives. *To test the hypothesis that the SCD EXPRESS™ intermittent pneumatic compression applied in combination with a four-layer bandage in patients with venous ulcers increases popliteal vein volume flow and velocity.*
Design. *Twenty limbs of 18 patients with venous leg ulcers were studied, median age 76 years. The Total Volume Flow (TVF) and the Peak Systolic Velocity (PSV) were recorded in the popliteal vein using duplex ultrasonography. Measurements were made (i) without bandage, (ii) with four layer bandage and (iii) following the application of the SCD Compression System on top of a four-layer bandage for at least 15 minutes.*
Results. *The median VCSS was 17 (range, 12–22) while the median VSDS for reflux was 4.5 (range, 1–7.5). The median TVF was 71 mL/min (inter-quartile range 57–101) without bandage, 112 (IQR 89–148) with four-layer bandage and 291 (IQR 241–392) with the addition of the SCD System* (P <.001, *Wilcoxon signed ranks test). The median PSV was 8.4 cm/* sec *(IQR 6.8–14) without bandage, 13 (9.0–19) with four-layer bandage and 27 (21–31) with the addition of the SCD System* (P <.001, *Wilcoxon signed ranks test). Both TVF and PSV increased slightly with the addition of the four-layer bandage. However, with the addition of the SCD System these parameters increased three fold.*
Conclusions. *The SCD EXPRESS Compression System accelerates venous flow in the legs of patients with venous ulcers already treated with a four-layer bandage. The combination of four-layer compression with the SCD System on healing venous ulcers needs to be tested by a clinical effectiveness study.*

Keywords: CVI; IPC; SCD EXPRESS compression system; Venous ulcers; 4-layer bandage.

Introduction

The prevalence of leg ulceration varies substantially. In the UK it has been reported to be approximately 0.38% in people older than 40 years,[1] The four-layer compression system (four-layer bandage; FLB) is currently the standard treatment in the UK.[2,3] and its cost effectiveness in healing venous ulcers has been shown.[4]

The aim of this study is to test the hypothesis that the combined use of the sequential compression device SCD EXPRESS™ Compression System[5] (Tyco Healthcare/Kendall, Mansfield, MA USA), in patients with venous ulcers increases significantly popliteal vein velocity and flow compared to the FLB alone. Such an increase would indicate that pneumatic leg compression (Intermittent Pneumatic Compression; IPC) is utilizing residual leg venous volume that the FLB has not managed to reduce. This additional haemodynamic improvement in patients with chronic venous leg ulcers may speed healing.

Patients and Methods

Ethics committee approval was obtained from the regional health authority for this prospective non-randomized study. Patients over 18 years of age, with active venous ulceration, C6 CEAP classification,[6] due to chronic venous insufficiency attending the leg ulcer clinic (Outpatient Department, at Charing Cross Hospital, London UK), and who gave their informed consent, were recruited in the study. Patients having other pathology contributing partially or wholly to their symptoms were excluded. For example, patients having mixed ulcers, with significant peripheral vascular disease, defined as an ankle/brachial systolic pressure index (ABPI) of <.9 or leg oedema due to cardiac or renal failure, metastatic malignancy or

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pulmonary oedema as a result of congestive heart failure were excluded. The inclusion of such patients in this preliminary study would not allow us to find the real impact of compression. Other exclusion criteria were clinically suspected or history of deep venous thrombosis (DVT) and/or pulmonary embolism (PE) within the past three months, active clinically suspected infection, and calf circumference (measured over the four-layer compression bandages) less than 33 cm or greater than 66 cm.

Methodology. A detailed medical history, physical examination, and lower limb venous colour duplex ultrasound was carried out to assess each leg and assign the venous clinical severity score (VCSS) and the reflux and obstruction components of the venous segmental disease score (VSDS).[7] The VCSS grades 9 clinical characteristics of chronic venous disease from 0 to 3 (absent, mild, moderate, severe) with specific criteria to avoid overlap or arbitrary scoring. The VSDS combines the anatomical and pathophysiological components of CEAP. Major venous segments are graded according to presence of reflux or obstruction.

Ultrasound scanning was used to examine the patients in the standing and sitting positions to assess the superficial and deep venous system of the legs for patency and presence of reflux, as previously described.[8] Reflux was induced by manual distal compression of the limb followed by sudden release, and was considered as significant when the duration of the retrograde flow was more than .5 seconds.[9]

The leg was routinely soaked in lukewarm water with Oilatum (Steifel Laboratories, UK) for 20 minutes and dried. This was followed by debridement and the application of ordinary kitchen cling film around it. After baseline measurements, we applied the "Charing Cross" four-layer bandage, comprising orthopedic padding, crepe, Elset™ (Medlock Medical Ltd, Oldham, UK) and 3M™ Coban™ (3M, St. Paul, MN, USA). This is designed to apply 40 mm Hg of pressure at the ankle, graduating to 17 mm Hg at the knee, sustained for a week.[2] The bandage was applied by the same experienced vascular nurse and measurements were repeated.

IPC was then applied on the leg. After 15 minutes the measurements were repeated. The IPC system has three calf chambers that inflate sequentially for 11 seconds. The maximum pressure during inflation in the most distal chamber is 45 mm Hg. A detailed description of the compression system has been published.[5]

Flow and velocity measurements. Flow and velocity measurements were performed with an ATL HDI 5000 scanner (Advanced Technology Laboratories Inc, Bothell, Wash).[10] With a linear broadband width 7—4 MHz transducer, a longitudinal scan of the popliteal vein just cephalad to the confluence of the lesser saphenous and popliteal veins was performed. The Doppler gate was placed in the middle of the vein with the sample volume centred on and completely insonating the vessel. The cursor was parallel to the direction of flow and a 60-degree angle of insonation was used at all times. The following ultrasound scan parameters were also kept constant: dynamic range, two-dimensional gray maps, persistence, frame rate, and wall filters.

The background of the ultrasound settings and the rationale for choosing the four second measurements is explained below. The Phillips 5000 ultrasound has the possibility of three sweep speed settings for the spectral Doppler. These give a possible volume flow sample of 2.5, 5 or 10 seconds. With increased duration of sample there is reduced accuracy of placement of cursor and therefore reduced accuracy of measurements. With application of IPC, although the activity of the IPC is 11 seconds, a five second screen sweep speed was chosen. Since there is an observer response time to freeze the screen post complete compression cycle, an interval of four seconds was selected to be recorded, on a sweep speed of five seconds per screen. The screen was frozen and measurements were recorded.

The maximum point of the augmented waveform constituted the peak velocity during compression i.e. the Peak Systolic Velocity (PSV). Total Volume Flow (TVF) was provided automatically by the equipment software, which took into account the diameter of the vein (measured with the on-screen callipers and used by the system to calculate the cross-sectional area) and the Time Average Mean Velocity (TAMV) over four seconds of the inflation period ($r^2 \times$TAMV).

Velocity, flow and venous diameter measurements (repeated five times and averaged) at the popliteal vein were measured with an ultrasound scanner during the following three stages of the study:

1. During resting in sitting position, with knees bent at an angle of approximately 110 degrees, without any form of compression applied.
2. Patients then had the four-layer compression bandage applied and resumed the sitting position as above.
3. Subsequently an IPC sleeve was placed on top of the FLB and the patient resumed the same sitting position. Knee-length sleeves were applied only on the affected leg; the IPC was activated and after at least 15 minutes of continuous compression to achieve haemodynamic equilibrium, volume flow and velocity were measured.

Gill suggested that repeating the measurements of flow several times and averaging the results can reduce the random errors to an acceptable level.[11] In the present study, the average of the five measurements of the total volume flow was based on the four measurements of each individual second and also this was compared to the average five measurements that were provided for the total four seconds by the inbuilt program of the duplex scanner.

Statistical analysis. The Kolmogorov-Smirnov test was used as a means of testing normal distribution of the data. Non-parametric tests were used because of non-normal distribution. Statistical significance between different groups was assessed by using the paired Wilcoxon signed-rank test. SPSS software for Windows, version 10 (SPSS Inc., Chicago, IL) was the statistical package used for statistical analysis. *P* values of less than 0.05 were considered to indicate statistical significance.

Results

Twenty lower limbs in 18 patients with active venous ulcer were studied. There were nine male and nine female, median age 76 years (range, 47–85). Regarding the CEAP classification, all patients were Cs6. The Etiology was primary in 4 and secondary in the remainder. The Anatomy ranged from As(2,3) to As(2,3,4) d(13,14,15,16) p(17,18). The Pathology was in all Pr and only one patient had also obstruction (Pr,o) and the score was three. The median VCSS was 17 (range, 12–22) while the median VSDS for reflux was 4.5 (range, 1–7.5). The sites of the legs studied were 11 left and nine right. The median circumference of the leg above the FLB was 42.5 cm (range, 35–52 cm). The patient's median BMI was 30.7 (range 17.6–45.9). The ABPI was >1 in all patients, apart from two that was >0.9.

The median TVF was 71 mL/min (inter-quartile range 57–101) without bandage, 112 (IQR 89–148) with four-layer bandage and 291 (IQR 241–392) with the addition of the SCD System ($P < .001$, Wilcoxon signed ranks test). (Fig. 1). The median PSV was 8.4 cm/sec (IQR 6.8–14) without bandage, 13 (IQR 9.0–19) with four-layer bandage and 27 (IQR 21–31) with the addition of the SCD System ($P < .001$, Wilcoxon signed ranks test). (Fig. 2). The addition of FLB increased both TVF and PSV however, the addition of the IPC increased these parameters three fold.

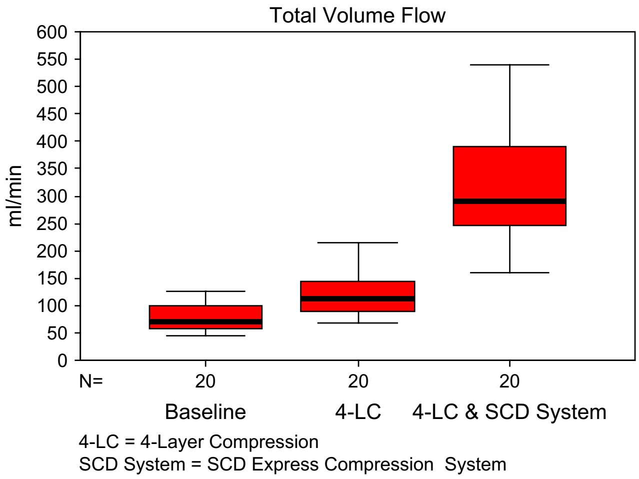

Fig. 1. Box and whisker plot of total volume flow showing the median and interquartile range (box) and range (whiskers) in mL/min at baseline, with four-layer compression and with four-layer compression plus SCD EXPRESS™ Compression System (all $P < .001$).

Discussion

Stanton *et al.*, in 1949 were the first researchers who demonstrated the effect of compression on the velocity of flow and the slowing of flow to anatomic abnormalities in the deep veins of the leg.[12] The application of local pressure of 20 to 35 mm Hg to the lower extremity of human subjects increased the velocity of venous flow (both in the superficial and deep venous systems), as measured by fluoroscopy, serial venograms, foot-to-tongue circulation times and limb venous circulation times. In their study, in six patients

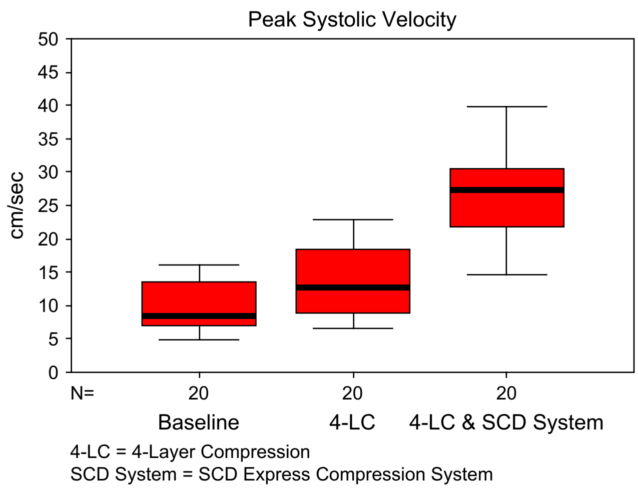

Fig. 2. Box and whisker plot of the peak systolic velocity showing the median and interquartile range (box) and range (whiskers) in cm/sec at baseline, with four-layer compression and with four-layer compression plus SCD EXPRESS™ Compression System (all $P < .001$).

the velocity of venous flow as judged from the foot-to-tongue and foot-to-pharynx circulation times was similarly accelerated whether the source of local compression was an inflatable legging, an elastic stocking or a carefully applied elastic bandage. Our study confirms the above as the FLB increased the TVF and PSV as compared to baseline and with the addition of the IPC the TVF and PSV in the popliteal vein increased even further.

The mechanism of action of passive, external compression is multifactorial.[13,14] Partsch *et al.*, have shown that like inelastic compression, the four-layer bandaging reduces venous filling index and venous volume only partially.[14] Based on their results there is room for improvement, but is it is unlikely that a compression profile higher than 40 mm Hg will be tolerated by most patients or be free of side effects.

Vowden performed an extensive review of the literature and concluded that the use of IPC in treating venous ulcers requires further study.[13] We identified ten such studies performed over 25 years, combining compression and IPC.[15–24] All these studies used different devices, methodology and follow-up and though, in their majority the results appear promising the number of patients involved and the time of follow-up are limited.

Digitized color-duplex sonography has a volume flow measurement error that is too high for single measurements in the individual patient for the method to be useful in clinical decision making, but sufficient for examinations of groups and comparison of groups.[25] In our study by repeating the measurement five times and obtaining the average as suggested by Gill, a more reproducible figure was obtained.[11]

Jeanneret *et al.*, compared measured versus calculated venous cross-sectional area in five healthy subjects in standing and lying position, while breathing normally and during a Valsalva manoeuvre.[26] With all measurements they found correlation coefficients (r) greater than .82, particularly in standing subjects, concluding that calculated venous area is accurate. The accuracy of the calculated versus measured readings was also confirmed in the present study.[27]

Christopoulos *et al.*, using Air-Plethysmography, demonstrated that with increasing values of reflux, as measured by the average filling rate of the veins in milliliters per second, on standing from the supine position, the incidence of ulceration increased.[28] It would be interesting to study whether there is a correlation between the increase of popliteal vein flow with application of IPC and leg ulcer healing rate.

The SCD EXPRESS Compression System accelerates venous flow in the legs of patients with venous ulcers already treated with a four-layer bandage. The combination of four-layer compression with the SCD System on healing venous ulcers needs to be tested by a clinical effectiveness study.

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