The efficacy of a new portable sequential compression device (SCD Express) in preventing venous stasis

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Objective: **It has been previously shown that the SCD Response Compression System, by sensing the postcompression refill time of the lower limbs, delivers more compression cycles over time, resulting in as much as a 76% increase in the total volume of blood expelled per hour. Extended indications for pneumatic compression have necessitated the introduction of portable devices. The aim of our study was to test the hemodynamic effectiveness of a new portable sequential compression system (the SCD Express), which has the ability to detect the individual refill time of the two lower limbs separately.**

Methods: **This was an open, controlled trial with 30 normal volunteers. The new SCD Express was compared with the SCD Response Compression System in the supine and semirecumbent positions.The refilling time sensed by the device was compared with that determined from velocity recordings of the superficial femoral vein using duplex ultrasonography. Baseline and augmented flow velocity and volume flow, including the total volume of blood expelled per hour during compression with the SCD Express, were compared with those produced by the SCD Response compression system in the same volunteers and positions.**

Results: **Both devices significantly increased venous flow velocity as much as 2.26 times baseline in supine position and 2.67 times baseline in semirecumbent position (all $P < .001$). There was a linear relationship between duplex ultrasonography–derived refill time and the SCD Express–derived refill time in both the supine ($r = 0.39$, $P = .03$) and semirecumbent ($r = 0.71$, $P < .001$) positions but not with the SCD Response. Refill time measured by the SCD Express device was significantly shorter and the cycle rate higher in comparison with the SCD Response in both positions. The single-cycle flow velocity and volume flow parameters generated by the two devices were similar in both positions. However, median (interquartile range) total volume of blood expelled per hour was slightly higher with the SCD Express device in the supine position (7206 mL/h [range, 5042-8437] vs 6712 mL/h [4941-10,676]; $P = .85$) and semirecumbent position (4588 mL/h [range, 3721-6252] vs 4262 mL/h [3520-5831]; $P = .22$). Peak volume of blood expelled per hour by the SCD Express device in the semirecumbent position was significantly increased by 10% in comparison with the SCD Response ($P = .03$).**

Conclusions: **Flow velocity and volume flow enhancement by the SCD Response and SCD Express were essentially similar. The latter, a portable device with optional battery power that detects the individual refill time of the lower limbs separately, is anticipated to be associated with improved overall compliance and therefore optimized thromboprophylaxis. Studies testing its potential for improved efficacy in preventing deep vein thrombosis are justified. (J Vasc Surg 2005;42:296-303.)**

Venous stasis, induced by prolonged leg immobilization, mainly during surgical procedures and the postoperative period, is responsible for a large number of potentially preventable cases of venous thromboembolism (VTE). Intermittent pneumatic compression (IPC) devices, which prevent venous stasis in the lower limbs, reduce the incidence of VTE.[1,2] IPC is particularly attractive because it is not associated with hemorrhagic complications.

Devices produced in the 1980s and early 1990s had a cycle of fixed compression and decompression periods. In addition, they were heavy, noisy, and powered by mains electricity. Recent technologic advances have enabled the production of devices that are smaller, portable, silent, and battery powered. Additionally, they offer customized compression based on the individual's venous refill time.[3] The aim of this study was to test the hemodynamic performance of a new portable IPC device (SCD Express, Tyco Healthcare/Kendall, MA), which uses a similar technology employed by the SCD Response. The latter, by detecting the individual's venous refill time, has been shown to achieve more compression cycles over time and therefore enhance leg venous flow by as much as 76%.[3] This combination of enhanced flow

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and portability could further increase the effectiveness of IPC in DVT prevention.

METHODS

Description of the SCD Response and SCD Express compression systems. A detailed description of the SCD Response Compression System has been published.[3] During the decompression period, the SCD Response Compression System uses a method similar to that of air plethysmography[4] to estimate the postcompression refilling of the veins. The refill time recorded is used to prevent premature compression of a leg, and the subsequent compression only commences when the veins in both legs are refilled. The new SCD Express uses a similar method, but, unlike the SCD Response, which measures the combined refill time of the two legs by means of a bifurcated tubing system, the SCD Express measures refill times by means of two different tubing systems, one for each leg. The SCD Express is smaller and has an optional battery power supporting full function for 6 to 8 hours. In addition, it is significantly lighter (3.5 lb without the power cord and 4.6 lb with the power cord) than the SCD Response (9 lb). The SCD Express and SCD Response sleeves have a similar design, the only difference being that the thigh chamber of the SCD Express KAMBIA sleeve can be removed when necessary to accommodate the period when the risk of VTE has decreased.

Subject selection and evaluation. Thirty "normal" subjects, 10 from each of the three age groups: 18 to 30 years, 31 to 50 years, and older than 50 years, were recruited; the male:female ratio was 1:1 in each group. Subjects were excluded if they were currently pregnant or breast-feeding or had any local leg condition with which sleeves would interfere such as dermatitis, vein ligation, gangrene, or recent skin graft; severe leg arteriosclerosis or other ischemic vascular disease (indicated by the absence of pedal pulses and/or a history of intermittent claudication); massive leg edema or pulmonary edema from congestive heart failure; suspected existing or previous VTE; or extreme leg deformity or size (thigh circumference <20 in or >28 in). Participants' legs were screened for occult venous disease (thrombosis and reflux) using duplex ultrasonography scanning. One leg per subject was tested (right leg in 15 subjects and left leg in the remaining 15 subjects). The case number determined the leg tested. The right leg was tested on the subjects with odd case numbers and the left leg was tested on the subjects with even case numbers, whereas the device and position sequences (supine and semirecumbent) were randomized. All testing was performed in a similar fashion and at the similar times of the day between the two groups to reduce variability. A 5-minute interval of no compression between devices and positions to establish equilibrium was allowed.

Duplex ultrasonography scan–derived refill time measurement. Details of our methodology have been previously published.[3,5] Briefly, when flow velocity is recorded with duplex ultrasonography scanning, the normal venous return in the lower limbs has a phasic pattern (respiratory, cardiac, or combined).[6] During the 11 seconds of leg compression, there is an augmentation of the normal venous velocity, but after the end of the compression, venous flow is practically undetectable, indicating a near-emptying of the veins of the lower leg. Some time is necessary for the veins to refill and flow to be detected. Progressively, the velocity of the venous return increases and when the veins are fully refilled, both the normal phasic pattern and velocity of venous return are re-established. The time necessary for the complete return of a normal phasic pattern of the femoral venous flow as determined with Doppler scanning was considered as the duplex ultrasonography scan–derived postcompression refill time; this reading was compared with the corresponding SCD Response–derived refill time or SCD Express–derived refill time. Although the SCD Express device measures and displays the refill time of both legs separately, to avoid any potential error, this was performed only on the leg studied. The sleeve of the contralateral leg was not connected to the SCD Express tubing system; during the calibration procedure, the SCD Express seals the outlet. To minimize potential error in the estimation of duplex ultrasonography scan–derived refill time due to extreme variations in the respiratory efforts, we asked all subjects to breath normally and gently.

Flow and velocity measurements. Flow and velocity measurements were performed using an ATL HDI 3000 scanner (Advanced Technology Laboratories Inc., Seattle, WA), as previously described.[3] Using a linear broadband width 7-4 MHz transducer, a longitudinal scan of the superficial femoral vein, just distal to the confluence of the profunda femoral vein, was performed, baseline velocity and flow pattern were identified, and both the spontaneous flow and augmented flow of 11 seconds were recorded. The maximal point of the spontaneous and augmented waveform constituted the peak baseline velocity and peak velocity (PV) during compression, respectively. Total volume flow (TVF) was provided automatically by the equipment software, taking into account the diameter of the vein (which was measured using the on-screen calipers and used by the system to calculate the cross-sectional area) and the time average mean velocity over the 11-second inflation period. Peak volume flow (PVF) was calculated in a similar manner as TVF using the 1-second interval around the PV. The total volume of blood expelled during compression over 1 hour and the corresponding peak volume per hour were calculated from these basic measurements and the individual cycling rate. The same principles were applied to determine spontaneous (baseline) flow parameters (PV, TVF, and PVF). Although both legs were compressed by the two types of devices during this second phase of the study, velocity and flow measurements were performed on one leg and repeated in the supine and semirecumbent positions using both compression systems. Measurements were performed with a 5-minute time delay after each device was applied to achieve physiologic equilibrium. Three consecutive measurements of velocity and flows were recorded, and the median value was calculated.

Table I. Spontaneous and augmented flow velocity and volume flow, including total and peak volume expelled per hour, in 30 subjects tested in the supine position; duplex ultrasonography–derived and device-derived refill times are also demonstrated

	SCD Response	*SCD Express*	*P*
Baseline TVF (mL/min)	223 (146-399)	261 (156-350)	.98
Baseline PVF (mL/min)	317 (178-466)	300 (205-488)	.72
Baseline PV (cm/s)	23 (17-32)	23 (16-29)	.63
Duplex refill time (s)	28 (25-30)	27 (25-29)	.79
Device refill time (s)	41 (35-45)	31 (29-34)	<.001
Cycling rate (cycles per hour)	66 (62-80)	84 (80-90)	<.001
Augmented TVF (mL/min)	548 (353-737)	481 (342-586)	.05
Augmented PVF (mL/min)	858 (572-1250)	847 (572-1000)	.38
Augmented PV (cm/s)	52 (36-80)	51 (39-57)	.46
Total volume per hour (mL)	6712 (4941-10,676)	7206 (5042-8437)	.85
Peak volume per hour (mL)	1034 (680-1407)	1209 (822-1412)	.29
TVF ratio	2.54 (1.78-3.26)	1.70 (1.49-2.37)	.07
PVF ratio	2.95 (2.00-4.11)	2.19 (1.78-3.81)	.42
PV ratio	2.34 (1.91-3.46)	2.20 (1.78-3.02)	.45

TVF, Total volume flow; *PVF,* peak volume flow; *PV,* peak velocity.
Results shown are median and interquartile range. Ratios represent the augmented/baseline fraction.

Table II. Spontaneous and augmented flow velocity and volume flow, including total and peak volume expelled per hour, in 30 subjects tested in the semirecumbent position; duplex ultrasonography–derived and device-derived refill times are also demonstrated

	SCD Response	*SCD Express*	*P*
Baseline TVF (mL/min)	79 (45-151)	86 (67-143)	.89
Baseline PVF (mL/min)	176 (99-230)	186 (93-245)	.38
Baseline PV (cm/s)	12 (9.1-15.0)	12 (9.2-14.3)	.69
Duplex refill time (s)	29 (27-33)	31 (26-35)	.66
Device refill time (s)	45 (38-50)	36 (32-43)	.001
Cycling rate (cycles per hour)	64 (59-71)	73 (66-82)	<.001
Augmented TVF (mL/min)	358 (294-514)	356 (259-456)	.33
Augmented PVF (mL/min)	777 (614-1010)	813 (579-982)	.93
Augmented PV (cm/s)	31 (28-39)	32 (27-35)	.24
Total volume per hour (mL)	4262 (3520-5831)	4588 (3721-6252)	.22
Peak volume per hour (mL)	842 (659-1067)	929 (699-1201)	.03
TVF ratio	3.87 (2.29-6.22)	3.74 (2.31-4.90)	.01
PVF ratio	3.94 (2.78-6.23)	4.56 (2.95-6.77)	.42
PV ratio	2.57 (2.25-3.45)	2.87 (2.00-3.67)	.75

TVF, Total volume flow; *PVF,* peak volume flow; *PV,* peak velocity.
Ratios represent the augmented/baseline fraction. Results shown are median and interquartile range.

Statistical analysis. The Kolmogorov-Smirnov test was used to test data for normal distribution. Nonparametric tests, Wilcoxon signed ranks test, Mann-Whitney test, Spearman correlation, and parametric tests (Pearson correlation) were used for statistical analysis, which was performed with the statistical package SPSS for Windows (version 11.5), Chicago, IL.

RESULTS

Five of the legs tested (17%) had venous incompetence on ultrasound scan. This was located in the deep veins in one case, the superficial veins in another case, the deep and superficial veins in a third case, the deep and perforating veins in a fourth case, and all three systems in the fifth case. Four contralateral legs (13%) had venous reflux, which was superficially located in two cases, affecting the deep and superficial venous system in one case and a Cockett's perforating vein in the fourth case. Superficial venous reflux was mainly segmental, apart from one case of short saphenous reflux; deep venous reflux involved mainly the gastrocnemial veins. In all cases, these were incidental findings without any symptoms or signs.

Median (interquartile range) age was 38 (range, 28-56.3) years. No significant difference between males and females was observed. No adverse events were encountered.

The results are shown in Tables I and II. Spontaneous (baseline) PV and volume flow measurements for the two devices were comparable in both positions ($P \geq .05$; Fig 1). The semirecumbent position significantly reduced spontaneous PV and volume flow compared with

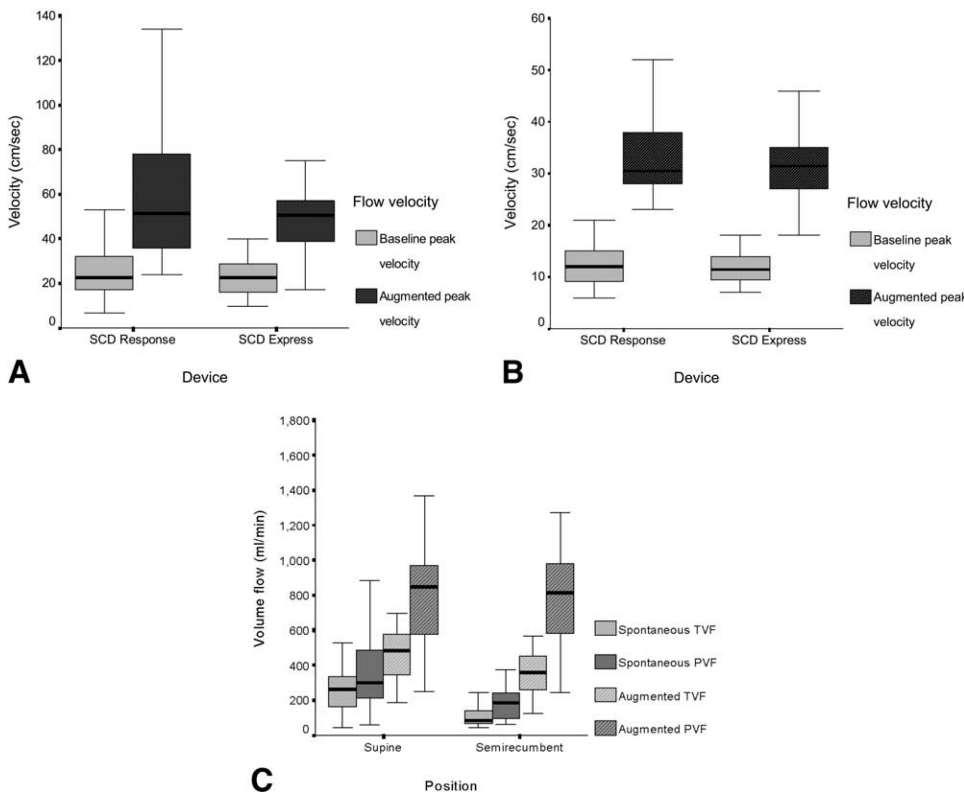

Fig 1. SCD Express and SCD Response devices were equivalent in increasing baseline flow velocity in both the supine (**A**) and semirecumbent (**B**) positions; all *P* values $<.01$. **C,** The effect of the SCD Express on total volume flow (TVF) and peak volume flow (PVF) in the supine and semirecumbent positions.

the supine position; the magnitude of this reduction varied from 38% to 67% (all *P* values $\leq.01$).

There was a linear relationship between duplex ultrasonography–derived refill time and SCD Express refill time in both the supine ($r = 0.39$, $P = .03$) and semirecumbent ($r = 0.71$, $P < .001$) positions (Fig 2). Correlation between duplex ultrasonography–derived refill time and SCD Response refill time was not significant in either position ($r = 0.16$, $P = .41$ and $r = 0.07$, $P = .71$, respectively). The difference between the two samples of duplex ultrasonography–derived refill time (obtained to be correlated with each device-derived refill time) in both positions was not significant (Tables I and II). In the supine position, SCD Express refill time was significantly shorter and compression rate significantly higher ($P < .001$) when compared with the corresponding SCD Response parameters. The same trend was found in semirecumbent position ($P = .001$).

Both devices enhanced spontaneous PV and volume flow (all *P* values $<.001$; Fig 1). PV increased 2.26 times with the SCD Response in the supine position and 2.67 times with the SCD Express in the semirecumbent position; flow enhancement was more impressive in the semirecumbent position (as much as 353%). Single-cycle flow and velocity data were all comparable (all *P* values $\geq.05$).

As a result of the increased single cycle flow and compression rate, total and peak volume expelled per hour were increased, as much as 16.9%, with the SCD Express compared with the SCD Response. The PVF expelled per hour in the semirecumbent position was in favor of the SCD Express ($P = .03$; Fig 3). All other differences were not statistically significant.

The presence of vascular reflux had no effect on device performance, only augmented PV [median (interquartile range)] with the SCD Express in the semirecumbent position increased from 31 (9) cm/s in patients with no venous reflux to 35 (14) cm/s in those with venous reflux ($P = .02$).

DISCUSSION

In this study, we tested a portable SCD device and demonstrated an improved correlation of the individual device–derived postcompression refill time with the duplex ultrasonography–derived refill time in comparison with the existing SCD Response Compression System. Several new features, such as the new thigh-length sleeve that can be easily converted to a knee-length sleeve, the straightforward compression of a single leg when this is necessary, and the portable nature of the new device, are anticipated to increase both patient compliance and ef-

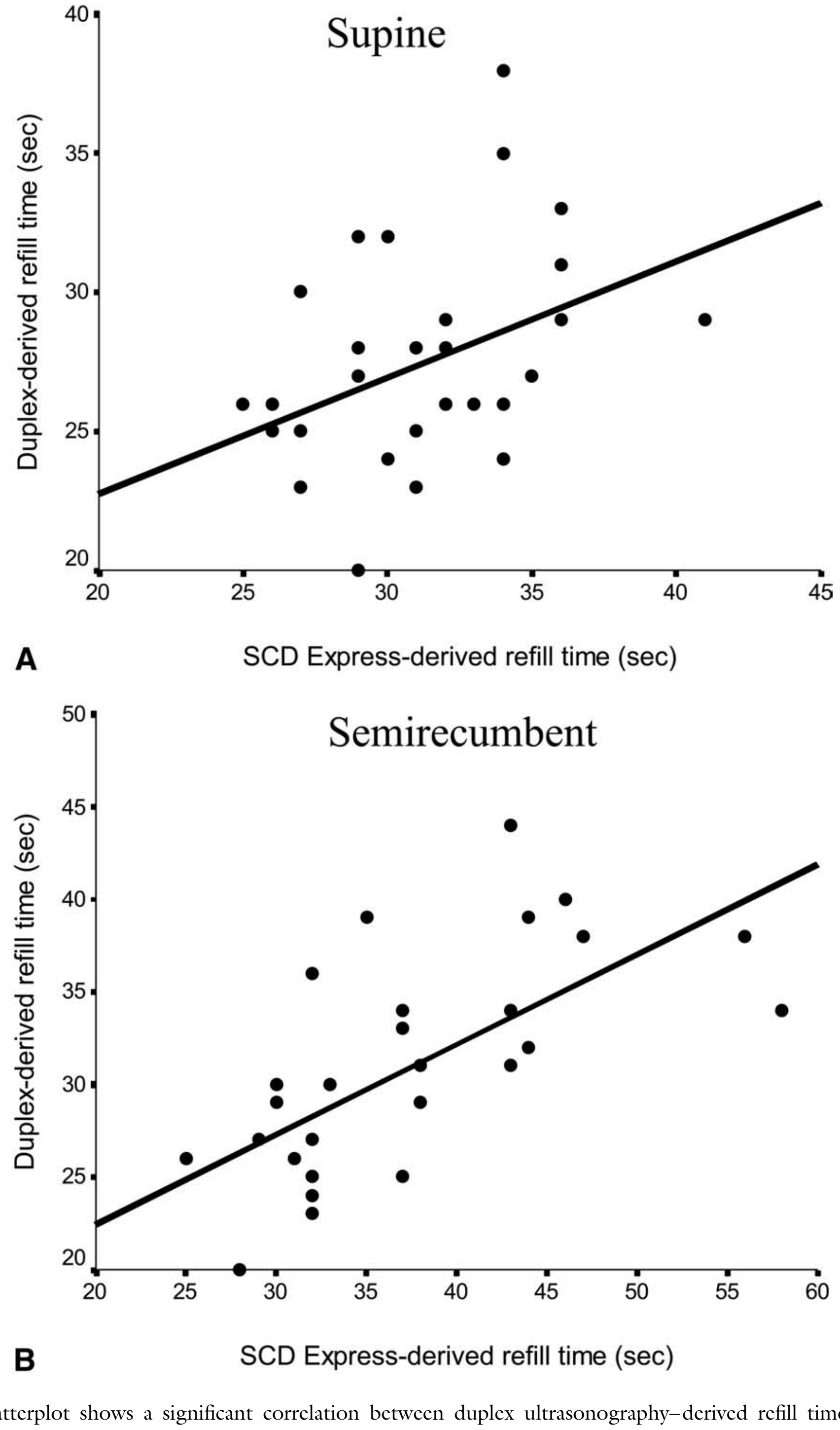

Fig 2. Scatterplot shows a significant correlation between duplex ultrasonography–derived refill time and SCD Express–derived refill time in both the supine (**A**) ($r = 0.39$, $P = .03$) and semirecumbent (**B**) ($r = 0.71$, $P < .001$) positions.

fectiveness in preventing VTE, although ideally these theoretical advantages should be proved by future studies. Compliance, defined as improved use for nursing and easier wearability for patients to increase the duration of compression time, will be improved with the SCD Express device because the device is battery powered and transportable. With the flexibility provided by the small, transportable controller, the SCD Express would be easier for nurses to use during application and management. In addition, the patient would be able to move

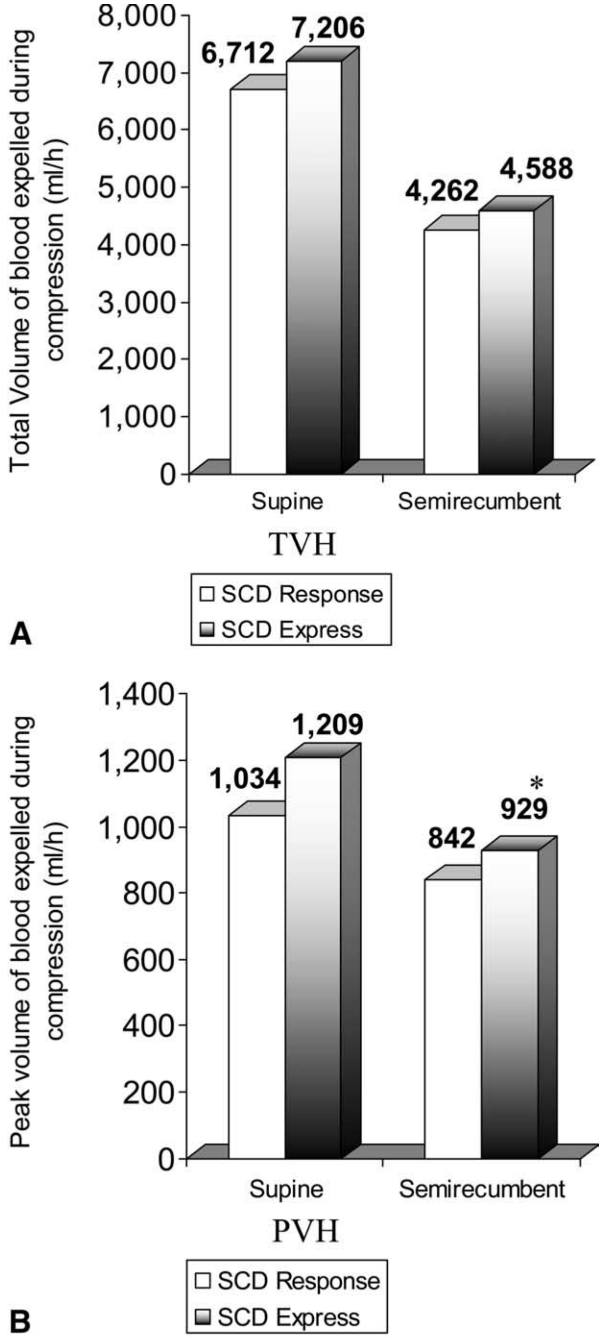

Fig 3. Comparison of total volume expelled per hour during compression (TVH) (**A**) and peak volume expelled per hour during compression (PVH) (**B**) by the SCD Response Compression System with that expelled by SCD Express in the supine and semirecumbent positions. *Asterisk* indicates significant difference between devices ($P = .03$), whereas the actual value of each group is shown on top of the corresponding bar.

about and be transported without removing the SCD Express sleeves and discontinuing prophylaxis, making the compression system easier to use throughout a patient's hospital stay.

IPC has a documented record in VTE prevention because it affects all three arms of Virchow's triad,[7] ie, hypercoagulopathy, venous stasis, and endothelial injury.[8-10] Because it lacks the hemorrhagic side effects of the anticoagulants, IPC is very popular in cases in which bleeding is increased, eg, trauma,[11] or potentially disastrous, eg, in the brain[12-14] or orthopedic surgery.[15] In a recent report on 25,000 participants of the Hip and Knee Registry, IPC boots or foot pumps were used in 50% of all cases and elastic stockings in approximately 60%.[15] Similarly, spinal bleeding, a known complication of spinal or epidural anesthesia in the presence of an anticoagulant and associated with technical errors during catheter insertion, favors the use of this physical modality.[16] Expanded indications include the combined use of physical and pharmacologic methods in very high-risk patients, which has been recommended by the two consensus publications on VTE prevention,[17,18] based on evidence from several studies.[19-23]

To avoid the compression of a leg before its veins have been fully refilled, the new device (SCD Express) uses the longest postcompression refill time of both legs. This is accomplished by measuring the postcompression time of the two legs separately; in contrast, the SCD Response measures the combined refilling of the two legs, the leg with the longest refill being the determinant of the applied refill time. The theoretical implications of this modification are unknown; in practice, however, duplex ultrasonography–derived refill time correlated with the refill time derived by SCD Express, in both the supine and semirecumbent positions, as shown in Figure 2, and, in addition, SCD Express–derived refill time was more sensitive to the different refilling ranges. This improved correlation between duplex ultrasonography–derived refill time and SCD-derived refill time (in favor of the SCD Express) could be viewed as evidence of the superiority of the new device, being the result of technologic improvement. We have previously reported a similar refill time association using the SCD Response in the sitting position.[3] Duplex ultrasonography–derived measurements represent the refilling of the axial veins, whereas device-refill time represents the refilling of the calf as a total, including the nonaxial gastrocnemial and soleal veins and the superficial venous system. Nonaxial calf veins are known to refill slowly,[24] and for that reason, device-derived refill time should be considered as the gold standard. Therefore, a perfect association between duplex ultrasonography–derived and device-derived refill time cannot be expected, especially in the supine position, in which the effect of respiratory movements on venous return introduces variability and could explain the lower correlation coefficient compared with the semirecumbent position.

The semirecumbent position (trunk elevated but the legs in horizontal position) decreased spontaneous PV and volume flow compared with the supine position. This expected finding is evidence that venous stasis occurs even with minor changes in body position. The sitting position has been described as associated with a decrease in flow velocity and an increase in vein diameter,[25] but information on flow changes is rather limited.[26,27] It is well established that increased leg blood volume and pressure in the dependent position activates the venoarteriolar reflex resulting in decreased leg perfusion and that evacuation of the leg veins and decreased venous pressure abolish the venoarteriolar reflex increasing arterial inflow. In our study, IPC increased PV and volume flow in both positions and tended to ameliorate the effect of the semirecumbent position. Lurie et al[27] have reported comparable results in the supine and 15-degree head-up or 15-degree head-down positions. In contrast, the semirecumbent position in the current study was virtually sitting on a couch with the legs being horizontal.

Device comparison in terms of augmented flow velocity and volume flow revealed comparable results. This was rather expected because device characteristics were similar. However, the total and peak volumes of flow expelled per hour were consistently in favor of the new SCD Express, but the overall difference was small. The reason for this difference was the increased cycling rate of the new SCD Express.

Incidental venous reflux had no effect on device performance or refill time measurements. This was expected because the segmental reflux found in our patients is unlikely to affect venous hemodynamics. Although venous reflux found by means of ultrasonography is very common in the general population,[28] it is unknown whether this is, like varicose veins, a risk factor for postoperative VTE.[29] In a previous study, we reported that refill time readings are significantly shorter in patients with severe bilateral venous reflux.[5]

In this study, we evaluated a portable IPC device, the main advantages being its small size and portability. Technologic improvement of IPC devices has improved their efficacy of moving blood over time.[3] However, it is unknown whether increased velocity (typically achieved by high-pressure, rapid inflation systems) or volume flow is better. Experts in this field support the latter[30]; probably prolonged compression (typically 11 seconds) is more efficient in reducing blood stasis in venous valve pockets,[31,32] which could explain the lower DVT rates when compared with the shorter compression of the higher compression systems.[33] DVT prevention studies are certainly necessary to evaluate the DVT reduction performance of this improved device.

In conclusion, flow velocity and volume flow enhancement by the SCD Response and SCD Express were very similar, apart from an increased compression rate and slightly increased peak volume of blood expelled per hour in the semirecumbent position. The latter, a quiet portable device with optional battery power that detects the individual refill time of the lower limbs separately, is anticipated to be associated with improved overall compliance and therefore optimized thromboprophylaxis. Further studies testing its potential for improved efficacy in preventing DVT are justified.

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