

The efficacy of the new SCD Response Compression System in the prevention of venous stasis

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Objective: The current commercially available sequential intermittent pneumatic compression device used for the prevention of deep venous thrombosis has a constant cycle of 11 seconds' compression and 60 seconds' deflation. This deflation period ensures that the veins are filled before the subsequent cycle begins. It has been suggested that in some positions (eg, semirecumbent or sitting) and with different patients (eg, those with venous reflux), refilling of the veins may occur much earlier than 60 seconds, and thus a more frequent cycle may be more effective in expelling blood proximally. The aim of the study was to test the effectiveness of a new sequential compression system (the SCD Response Compression System), which has the ability to detect the change in the venous volume and to respond by initiating the subsequent cycle when the veins are substantially full.

Methods: In an open controlled trial at an academic vascular laboratory, the SCD Response Compression System was tested against the existing SCD Sequel Compression System in 12 healthy volunteers who were in supine, semirecumbent, and sitting positions. The refilling time sensed by the device was compared with that determined from recordings of femoral vein flow velocity by the use of duplex ultrasound scan. The total volume of blood expelled per hour during compression was compared with that produced by the existing SCD system in the same volunteers and positions.

Results: The refilling time determined automatically by the SCD Response Compression System varied from 24 to 60 seconds in the subjects tested, demonstrating individual patient variation. The refilling time (mean \pm SD) in the sitting position was 40.6 ± 10.0 seconds, which was significantly longer ($P < .001$) than that measured in the supine and semirecumbent positions, 33.8 ± 4.1 and 35.6 ± 4.9 seconds, respectively. There was a linear relationship between the duplex scan-derived refill time (mean of 6 readings per leg) and the SCD Response device-derived refill time ($r = 0.85$, $P < .001$). The total volume of blood (mean \pm SD) expelled per hour by the existing SCD Sequel device in the supine, semirecumbent, and sitting positions was 2.23 ± 0.90 L/h, 2.47 ± 0.86 L/h, and 3.28 ± 1.24 L/h, respectively. The SCD Response device increased the volume expelled to 3.92 ± 1.60 L/h or a 76% increase ($P = .001$) in the supine position, to 3.93 ± 1.55 L/h or a 59% increase ($P = .001$) in the semirecumbent position, and to 3.97 ± 1.42 L/h or a 21% increase ($P = .026$) in the sitting position.

Conclusions: By achieving more appropriately timed compression cycles over time, the new SCD Response System is effective in preventing venous stasis by means of a new method that improves on the clinically documented effectiveness of the existing SCD system. Further studies testing its potential for improved efficacy in preventing deep venous thrombosis are justified. (J Vasc Surg 2000;32:932-40.)

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Deep venous thrombosis (DVT), a common postoperative complication, especially after orthopedic surgery, carries a significant morbidity in both the short term (pulmonary embolism) and the long term (post-thrombotic syndrome). Among the various prophylactic measures, elastic compression, intermittent pneumatic compression (IPC) of the legs, and low molecular weight heparin are the most effective, alone or in combination.¹ IPC devices can apply calf compression only, calf and thigh uniform compression, calf and thigh sequential compression, or foot compression.²⁻⁸ Despite the meticulous and often combined use of these prophylactic methods, DVT remains unacceptably prevalent, especially in high-risk groups.⁹ In the case of IPC, this could be due to suboptimal control of venous stasis, which explains why many authors have already optimized the compression profile of the intermittent pneumatic devices, including inflation pressure, slope of pressure, and sleeve type.^{10,11} However, the refilling of the veins during the deflation period has not been taken into account in the design of any commercially available IPC device, which explains why a fixed inflation-deflation pattern (for example, 11 and 60 seconds, respectively) has always been used. In only one experimental study¹² has an individual postcompression refill time been measured, but the complex nature of this procedure precluded any practical application.

Lower limb venous hemodynamics, including refill time, vary depending on the presence of venous disease (reflux or obstruction), position, daily activity, postoperative day, and the idiosyncrasy of the particular individual.¹³⁻¹⁶ This variation concerns not only the refill time of the leg veins when moving into the dependent position, but also the postcompression refill time, which varies significantly among apparently healthy subjects and is also significantly shorter in the presence of venous disease.¹⁷ Compressing the legs according to this individual refill time should theoretically lead to improved pulsatile flow and decreased venous stasis. Thus, measurement of the venous refill time and adjustment of the deflation period may lead to more compression cycles over time, which increases the total amount of blood expelled during the periods of compression. At the same time, this adjustment would eliminate and prevent ineffective premature cycles on a nonfilled venous system, which could have happened by simply increasing the frequency of cycling.

The aim of the current study was to test the ability of a new IPC device, SCD Response Compression System (Kendall Healthcare Products Co, Mansfield, Mass), in sensing the individual postcompression

refill time and its variability in various positions and also its effectiveness in making adjustments as a result of positioning. The final end point was to compare the effect of the new compression system on venous return with that of the current sequential compression system (SCD Sequel Compression System; Kendall Healthcare Products Co, Mansfield, Mass). The demonstration of a decreased venous stasis would justify further studies, which would explore the possibility of the SCD Response system's improved efficacy in the prevention of DVT.

METHODS

Description of the SCD Response Compression System. A method similar to segmental air plethysmography¹³ is used to estimate the postcompression refilling of the leg veins and the refill time by the SCD Response Compression System. The main principle is based on the measurement of the volume changes in the lower limb. Changes in the volume of the leg as a result of the filling or emptying of the veins produce corresponding changes in the pressure of the leg chamber. The sleeves used in sequential compression usually consist of three air chambers: lower calf, upper calf, and lower thigh, which are inflated sequentially.¹⁰ During the early postcompression period, when assessment of postcompression refill time is performed, the upper calf chamber is kept inflated at a baseline contact pressure level of 6 mm Hg. This baseline contact pressure is universal in all leg sizes and can be maintained in all positions, whereas no tourniquet effect could be demonstrated in our preliminary studies. The increasing volume of the leg due to venous refill leads to an increase in the pressure of this sensing cuff. Progressively, toward the end of venous refilling, a plateau in the pressure-time curve is reached. The time required to reach this plateau is the *refilling time*. The longer refill time between both legs is used to prevent compressing one leg before the actual refill is complete.

The compression profile of both the current and the new sequential compression systems is the same, with 11 seconds of sequential inflation of three chambers and a maximum pressure during inflation at the lower calf chamber of 45 mm Hg. The same type of commercially available thigh-length sleeves was used to test both devices throughout the whole experiment.

Duplex scan-derived refill time measurement. When flow velocity is recorded with duplex scanning, the normal venous return in the lower limbs has a phasic pattern (respiratory, cardiac, or combined¹⁸). During the 11 seconds of leg compression,

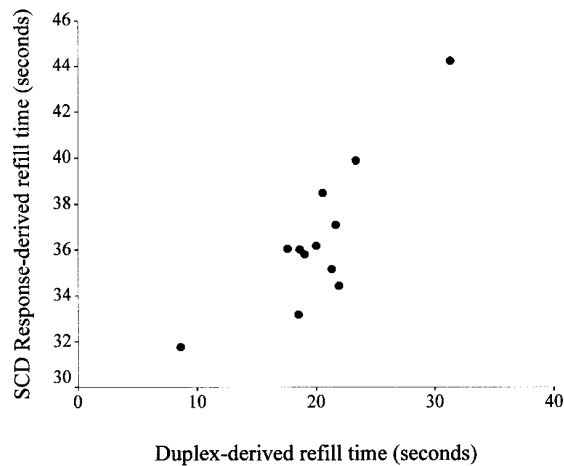


Fig 1. Scatter plot showing linear relationship between duplex scan–derived refill time and SCD Response–derived refill time in 12 patients ($r = 0.85$, $P < .001$). Each *dot* represents one leg and is the mean of readings in all positions (at least 6 readings per leg).

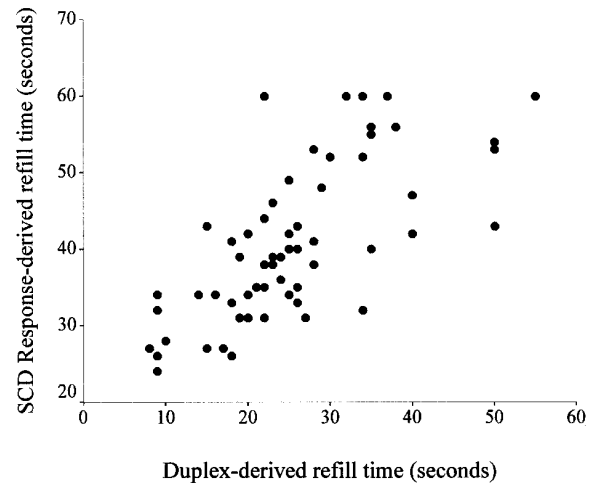


Fig 2. Scatter plot showing linear relationship between duplex scan–derived refill time and SCD Response–derived refill time in sitting position ($r = 0.70$, $P < .001$).

there is an augmentation of the normal venous velocity, but after the end of the compression, venous return is practically undetectable. Some time is necessary for the veins to become filled and flow to be detected. Progressively, the velocity of the venous return is increasing, and when the veins are fully refilled, both the normal phasic pattern and maximum velocity of venous return have recovered. The time necessary for the complete return of a normal phasic pattern of the femoral venous flow as determined with duplex Doppler scan was considered as the duplex scan–derived postcompression refill time, which has also been used in the past as an estimation of venous refilling.¹⁹ To minimize potential error introduction in the estimation of duplex scan–derived refill time due to extreme variations in the respiratory efforts, we asked all subjects to stay relaxed. Additionally, we did not consider extraordinary and abrupt changes in the baseline venous velocity due to vigorous respiratory efforts.

Flow and velocity measurements. Flow and velocity measurements were performed with an ATL HDI 3000 scanner (Advanced Technology Laboratories Inc, Bothell, Wash). With 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 the augmented flow of 11 seconds was recorded. 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 maximum point of the augmented waveform constituted the peak velocity during compression. Total volume flow was provided automatically by the equipment software, which took into account the diameter of the vein (which was measured with 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 was calculated in a similar manner as total volume flow with the 1-second interval around the peak velocity. In case of two or three peak velocities (corresponding to the inflation of the three chambers), all were checked, and the highest flow was registered as the peak volume flow. All measurements were repeated while subjects were in the supine, semirecumbent, and sitting positions, and both types of SCD systems were used. Four to six consecutive measurements (median, 5) of velocity or flows were recorded and the mean value calculated. The total volume of blood expelled over 1 hour and the corresponding peak volume per hour were calculated from these basic measurements and the individual deflation time.

Patient selection and evaluation. The study was performed in 12 healthy subjects, 3 men and 9

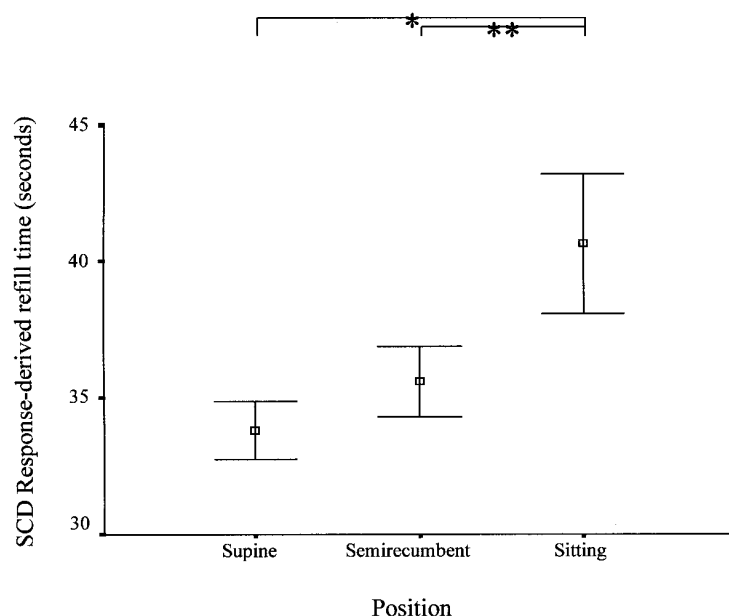


Fig 3. SCD Response-derived refill time (mean and 95% CI) in supine, semirecumbent, and sitting positions. * $P < .001$; ** $P = .001$.

Augmented venous outflow data generated by SCD Response Compression System versus SCD Sequel System in supine, semirecumbent, and sitting positions

Position	SCD type	Peak velocity (cm/s)	Total volume flow (mL/min)	Peak volume flow (mL/min)	Total volume of blood expelled during compression (L/h)	Peak volume of blood expelled during compression (L/h)
Supine	Sequel	44.5 ± 12.4	240.3 ± 96.7	418.2 ± 133.2	2.23 ± 0.90	0.35 ± 0.11
	Response	41.6 ± 10.3	260.2 ± 107.0	410.6 ± 130.5	3.92 ± 1.60*	0.56 ± 0.18*
Semirecumbent	Sequel	34.2 ± 5.2	266.2 ± 92.2	497.8 ± 151.2	2.47 ± 0.86	0.42 ± 0.13
	Response	30.7 ± 7.4	263.5 ± 104.4	470.7 ± 155.4	3.93 ± 1.55*	0.64 ± 0.22*
Sitting	Sequel	30.1 ± 8.8*	352.9 ± 133.4†	653.1 ± 216.9*	3.28 ± 1.24	0.55 ± 0.18
	Response	23.9 ± 6.4	274.1 ± 105.4	466.4 ± 191.2	3.97 ± 1.42‡	0.61 ± 0.22

Results shown as mean ± SD.

* $P < .01$.

† $P < .05$.

‡ $P < .02$.

women. Their mean age was 30 years (range, 22-40 years). On the basis of each subject's history, physical examination, and lower limb venous duplex ultrasound scan, we identified and excluded subjects with venous disease and those with duplication of the superficial femoral vein at the level where measurements were performed, which would preclude an accurate estimation of global venous return. Additional exclusion criteria included the presence of a local leg condition interfering with sleeve placement, such as dermatitis, ischemic vascular disease, extreme leg deformity, or edema, and a history of congestive

heart failure. All subjects gave their informed consent. Both the study protocol and the informed consent were approved by the Institutional Review Board.

All flow-velocity and duplex scan-derived refill time measurements were preferentially done on a subject's right leg. This was feasible in all but one because of exaggerated spontaneous pulsatile flow in the right femoral vein. All measurements were repeated while subjects were in the supine, semirecumbent, and sitting positions.

Statistical analysis. The Kolmogorov-Smirnov test was used to test normal distribution of the data.

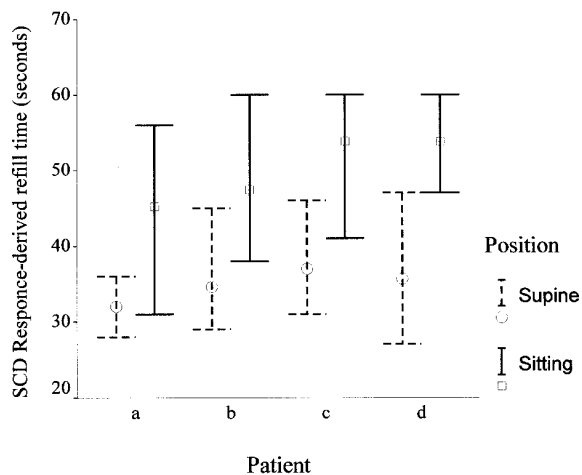


Fig 4. The difference at SCD Response-derived refill time between the supine and sitting position exceeded 10 seconds in four patients (a-d). Results shown as mean and range.

In such a case, statistical significance among different groups was assessed with one-way analysis of variance and the paired and the unpaired *t* test. The Pearson correlation coefficient method was used to correlate refill time measurements. SPSS for Windows, version 8, (SPSS, Inc, Chicago, Ill) was the statistical package used for statistical analysis. *P* values of .05 or less were considered statistically significant.

RESULTS

A linear relationship ($r = 0.85$, $P < .001$) between the duplex scan-derived refill time (mean of readings in all positions, at least 6 readings per leg) and the SCD Response device-derived refill time was found and is shown in Fig 1. The correlation between the duplex scan-derived and the SCD Response device-derived refill times in the sitting position, where the well-formed column of the SCD Response device-derived refilling time varied from 24 to 60 seconds in the subjects tested, demonstrating individual patient variation. This variation is further demonstrated by refill time changes as a result of position: 27 to 47 seconds in the supine, 27 to 49 in the semirecumbent, and 24 to 60 seconds in the sitting positions. The refill time measurements of healthy volunteers in the sitting position were found to be prolonged when compared with those of the supine or semirecumbent position (Fig 3). The mean \pm SD refilling time in the

sitting position was 40.6 ± 10.0 seconds, which was significantly prolonged ($P < .001$) when compared with that measured in the supine (33.8 ± 4.1 seconds) and semirecumbent positions (35.6 ± 4.9 seconds). This difference, being more than 10 seconds, was prominent in four subjects (Fig 4).

The results of the hemodynamic comparison of the two SCD devices are shown in the Table. Significantly higher blood volume was expelled per hour by the SCD Response Compression System in comparison with the SCD Sequel System. The SCD Response device increased the total volume of blood expelled per hour by 76% ($P = .001$) in the supine, 59% ($P = .001$) in the semirecumbent, and 21% ($P = .026$) in the sitting positions (Fig 5). A similar increase in the peak volume of blood expelled during compression periods per hour was 60% ($P = .002$), 52.4% ($P = .002$), and 10.9% ($P = .29$), respectively (Fig 6).

Despite the significantly shorter cycles when the SCD Response Compression System was used, no difference was found among the single cycle parameters: total volume flow, peak volume flow, or peak velocity generated by the two types of SCD compression devices in the supine or semirecumbent position, which implies that the leg veins were refilled when the next cycle began. When the SCD Sequel System was used, total volume flow, peak volume flow, and peak velocity were marginally higher only in the sitting position.

Peak velocity was substantially higher during compression in the supine position when compared with those of semirecumbent or sitting positions, regardless of the device type ($P \leq .005$ in all comparisons). However, peak velocity was very similar and had the same pattern in both devices.

DISCUSSION

In the current study, we investigated the effect on venous hemodynamics of a new type of sequential compression system. IPC of the legs^{2,8,10} has been developed to prevent venous stasis, which can be described as decreased venous return due to obstruction or reflux, a well-known precipitating factor of DVT.²⁰ Sequential compression systems prevent venous stasis by increasing the venous pulsatile flow and decreasing venous pooling, which happens during immobilization or surgery, even in the absence of overt venous disease.^{10,21-23} General anesthesia, for example, leads to generalized venodilation and subsequent reduction in spontaneous venous velocity, and individuals with excessive operative venodilation develop DVT more frequently.^{22,23} The new device was developed to detect these changing and individual features of venous stasis.

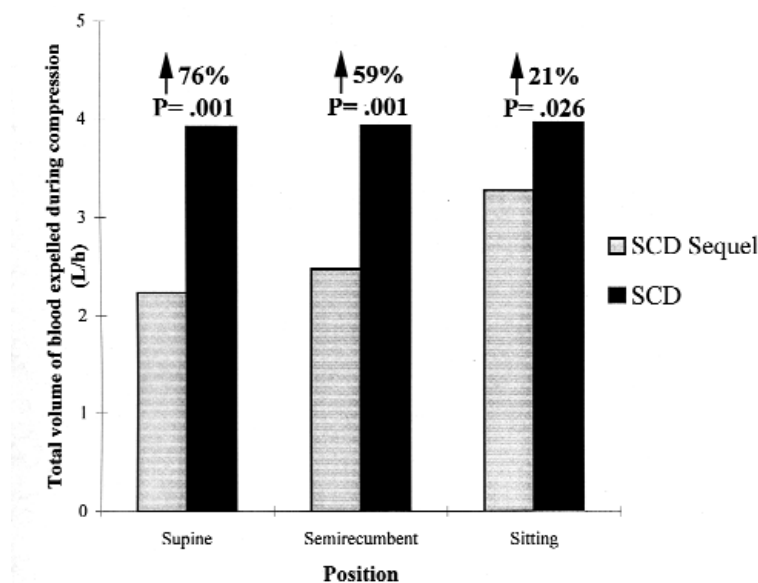


Fig 5. Comparison of total volume expelled per hour during compression by SCD Response Compression System with that expelled by SCD Sequel Compression System, in supine, semirecumbent, and sitting positions. *Arrows* indicate the percentage increase with SCD Response.

The efficacy of IPC in reducing the risk of DVT (on average, 64% in orthopedic surgery) is well established and comparable with that achieved when heparin is used.^{1,24} However, the fact that there is no absolute prophylactic measure explains the continuing necessity for further investigation into a better understanding of DVT pathophysiology and enhanced control of the precipitating factors. In the current study, we tested a new device for IPC that is able to sense the refilling of the veins and to apply an individual inflation-deflation pattern. The settings of the SCD Sequel System we used as the control in this study were an 11-second inflation period followed by a 60-second period of cuff deflation to allow the veins to refill, longer than necessary for some patients. These time settings and the inflating pressure settings were based on studies performed with electromagnetic flow meters²⁵ or velocity measurements using continuous wave Doppler¹⁰; however, the deflation period settings were rather arbitrarily chosen, taking into account average measurements rather than individual measurements. Kamm et al¹² measured for the first time the individual postcompression refill time using a radionuclide-gated imaging technique and found the postcompression refill time of leg veins of healthy volunteers to be between 30 and 50 seconds, quite similar to our results but certainly shorter than the fixed 60-second interval between

compression cycles used by the current SCD system. Although experimental, their work should be considered as a significant contribution in this field.

The new system uses a technique similar to segmental air plethysmography to determine the individual's refill time. During the early deflation period when refill time was estimated, a baseline air pressure of 6 mm Hg was applied to the upper-calf sensing cuff, because a minimum cuff pressure is necessary to ensure optimum contact of the sleeves to the calf. Preliminary prototype studies excluded any tourniquet effect of this pressure.

A significant correlation was found between the duplex scan-derived refill time and the SCD Response-derived refill time. This was prominent in the sitting position where the well-formed column of blood between the thigh and the calf allowed more precise refill time measurements. We used duplex scan-derived refill time measurements as an estimate of venous refilling. However, these measurements represent the refilling of the axial veins, whereas the Response-derived refill time represents the refilling of the calf as a whole, including the nonaxial gastrocnemial and soleal veins and the superficial venous system. Nonaxial calf veins are known to refill slowly¹⁰ and for that reason, Response-derived refill time should be considered as more accurate.

Not only the mean refill time but also its maximum values were significantly higher in the sitting

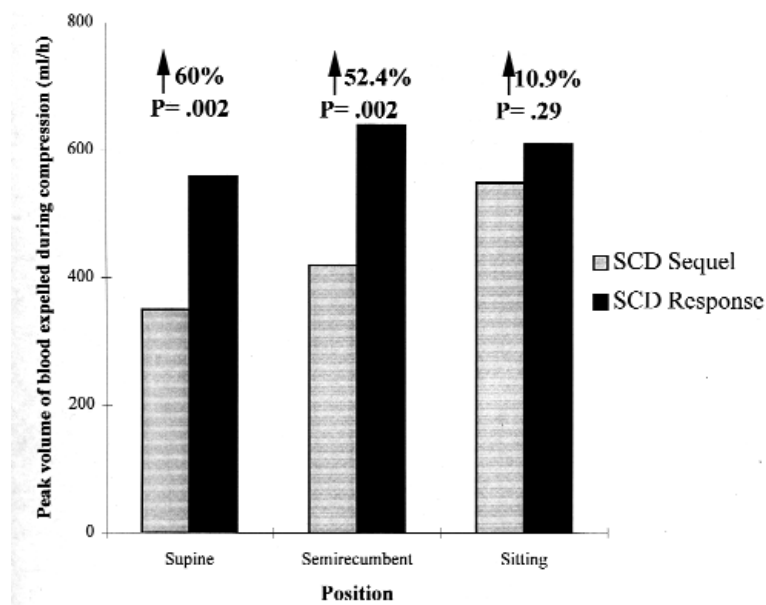


Fig 6. Comparison of peak volume expelled per hour during compression by SCD Response Compression System with that expelled by SCD Sequel Compression System, in supine, semirecumbent, and sitting positions. Arrows indicate the percentage increase with the SCD Response.

position. The reason for the postcompression refill time being longer in the sitting position compared with the supine position is probably the increased capacity of the leg veins²⁶ in association with the decreased arterial inflow due to the so-called venoarteriolar reflex²⁷; the latter has been described as a local vasoconstrictor response of the arterioles or the precapillary sphincter of both subcutaneous and skeletal muscle tissue during venous stasis, including passive postural changes, to maintain constant flow.^{27,28} This reaction could be prominent in the four subjects who had the prolonged refill time.

The total volume of blood expelled per hour by the SCD Response System in comparison with the SCD Sequel System was increased by 76% in the supine and 59% in the semirecumbent positions. The increased frequency of compression cycles due to a shorter deflation period in combination with a filled venous system, as evidenced by the unaffected total volume flow per cycle, explains the increase in the volume of blood expelled per hour that we found. A simple increase in the frequency of cycling cannot achieve the same results as the new system because premature cycles on a nonfilled venous system could happen, given the wide range of the Response-derived refill time, and this is the major difference between the new and the existing devices. The SCD Response Compression System is achieving cycles as

frequently as the refilling of the veins permit. Furthermore, the blood volume expelled per hour by the SCD Response Compression System in all three positions was about the same (Fig 5); this implies that when the Response Compression System is used and regardless of the individual's position, a maximum augmentation of venous outflow is achieved. This is further evidence of the superior hemodynamic performance of the new device, which is probably explained by the ideal coupling of the compression pattern with the individual refill time.

The peak volume of blood expelled per hour by the Response Compression System was also increased. This is further evidence of the better hemodynamic abilities of the new device, and for that reason, it can be hypothesized that when the Response Compression System is used, the washing out of stagnant hypoxic blood from the venous valve pockets or the soleal veins is enhanced. That most cases of postoperative DVT start there²⁹⁻³¹ is not surprising, because venous stasis is more prominent at these specific sites of the venous system.^{32,33}

It is expected that the frequent cycles of the Response Compression System are more efficient in preventing venous stasis than the standard settings of the existing device. With the current SCD system, inflation accounts for only 15% (11 seconds) of the total duration of the cycle (71 seconds). The new

system can achieve a better percentage of compression periods, as high as 31% (cycle of 35 seconds), in the current study. This is accompanied by an improvement in preventing venous stasis.

We found lower peak velocities in the sitting position. This is to be expected because the height of the hydrostatic column of the blood, which the expelled blood has to overcome, is significant in the case of the sitting position. Spontaneous flow in this position is otherwise low,³⁴ and thus, the percent increase in venous flow velocity is much higher. Despite the lower peak velocity in the sitting position, the total volume of blood expelled per hour by the SCD Response System was higher.

The reproducibility of venous flow measurements is not poor,³⁵ and in our study the coefficient of variation of total volume flow measurements varied between 3.3% and 22.3% (mean, 11.8%). To minimize the random error in venous flow measurements due to venous diameter changes during the respiratory cycle, we have averaged four to six consecutive measurements. To decrease the systemic error of flow measurements, we compared the two types of SCDs as soon as a 5-minute interval, necessary for hemodynamic equilibrium, was over. Furthermore, the error of flow estimations is low when comparing groups, like our study, instead of using individual flow results.³⁶

The new device has the ability to assess post-compression refill time of both legs; for practical reasons the longest refill time of both legs was used. This would avoid the compression of a leg before its veins have been fully refilled. In healthy subjects also, the difference in the refill time between the two legs is not expected to be significant. This difference would be of some significance in cases of venous reflux (superficial or deep) and mainly in the sitting position. Although such patients were not included in the current study, a shorter refill time and a subsequently much higher percent increase in the total volume of blood expelled per hour by the Response Compression System in comparison with the SCD Sequel System are expected. We have not had any complaints when compressing frequently; however, the manufacturer has built in a low cutoff point of a minimum 20 seconds' deflation time. Additionally, the new device is not allowed to have a longer deflation period than the 60 seconds, like in the existing SCD devices.

Obviously, DVT and pulmonary embolism are the main end points when testing different types of IPC devices. Therefore, DVT prevention studies^{6,37} in which the efficacy of the new system is tested are

justified. Such studies could compare different SCD types or the Response Compression System against other known prophylactic methods, such as low molecular weight heparin.

In conclusion, by achieving more compression cycles over time, the SCD Response Compression System was found to be much more effective in preventing stasis than the current SCD Sequel Compression System. The new system-assisted sensing of the venous refill time was found to permit individual adjustment of the deflation pattern. The resulting increased venous outflow was produced by the timing of the compression period to a filled venous system. Further studies exploring the possibility of improved efficacy in preventing DVT are justified.

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